UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION *This document relates to:* *Carol J. Williams, et al.*, No. 3:19-cv-18778 *Linda H. Hill*, No. 3:18-cv-08344 *Bobbie N. Landreth*, No. 3:17-cv-11788 *Michael Scroggins o/b/o Bertha M. Walton*, No. 3:18-cv-12766	**MDL No. 2738 (FLW) (LHG)**

CERTIFICATION OF KATHLEEN FRAZIER, ESQ. IN SUPPORT OF DEFENDANTS JOHNSON & JOHNSON AND JOHNSON & JOHNSON CONSUMER INC.'S OMNIBUS MOTION FOR SUMMARY JUDGMENT

1. I am an attorney of the state of Texas and am associated with the law firm Shook, Hardy & Bacon, L.L.P., counsel for Johnson & Johnson and Johnson & Johnson Consumer Inc. (collectively "JJCI") in the above-captioned matter. The facts stated in this Declaration are true of my own personal knowledge, except as to any matters stated on information and belief, and as to those matters, I am informed

and believe them to be true. I submit this Declaration in support of JJCI's Omnibus Motion for Summary Judgment dated June 18, 2021.

2. Plaintiffs alleging that JJCI talc products caused their ovarian cancer began filing lawsuits against the J&J defendants as early as December 2009.

3. The number of talc cases filed each year increased beginning in 2014, as reflected in the chart below:

Month/Year	Cases Served	Plaintiffs Served	Cases Filed	Plaintiffs Filed
2014	46	426	70	450
2015	131	907	136	913
2016	324	2081	425	2401
2017	4824	6300	5848	7360

4. The first jury verdict against JJCI – *Berg* – occurred in October 2013.

5. The first complaint in New Jersey was filed on January 31, 2014. Plaintiffs' co-lead counsel in the MDL, the Beasley Allen firm, filed their first complaint on April 28, 2014.

6. In 2016, there were a trio of jury trials in St. Louis – *Fox*, *Ristesund*, and *Giannecchini* – all resulting in multi-million dollar jury verdicts. All were later reversed on appeal.

7. Attorney advertising for talc claims had begun at least as early as 2014. In early 2016, it is estimated plaintiffs' attorneys were spending between $1 million

and $4.5 million per month. Attorney advertising occurred online, on radio, and on television. By April 2020, plaintiffs' attorneys had spent an estimated $63 million to air more than 175,000 TV ads touting their allegations and soliciting plaintiffs. Attorney advertising occurred online, on radio, and on television.

8. In 2014, there were 70 cases filed on behalf of 450 plaintiffs. In 2015, 136 cases were filed on behalf of 913 plaintiffs. In 2016, 425 cases were filed on behalf of 2,401 plaintiffs

9. Attached hereto as **Exhibit A** is a true and correct copy of the *Drugwatch* article "Jury Orders J&J to Pay $72M in Ovarian Cancer Talcum Powder Case," authored by Michelle Llamas, dated February 24, 2016, and available at https://www.drugwatch.com/news/2016/02/24/jj-to-pay-72m-in-ovarian-cancer-talcum-powder-case/.

10. Attached hereto as **Exhibit B** is a true and correct copy of *Reuters* article "Big Verdict Doesn't Assure More Wins for Plaintiffs in Talc-Cancer Cases," authored by Jessica Dye, dated February 26, 2016 and available at https://www.reuters.com/article/us-johnson-johnson-talc-cancer/big-verdict-doesnt-assure-more-wins-for-plaintiffs-in-talc-cancer-cases-idUSKCN0VZ1JS.

11. Attached hereto as **Exhibit C** is a true and correct copy of the *New York Post* article "I Turned Down $1M from Johnson & Johnson, and Blew the Whistle Instead," authored by Jane Ridley, dated March 2, 2016, and available at

https://nypost.com/2016/03/02/johnson-johnson-hid-the-dangers-of-talc-and-i-helped-blow-the-whistle/.

12. Attached hereto as **Exhibit D** is a true and correct copy of the *St. Louis Business Journal* cover story, "Jim Onder's $72 Million Baby Powder Win," authored by Greg Edwards, and dated March 11-17, 2016.

13. Attached hereto as **Exhibit E** is a true and correct copy of *Gaming the System: How Lawsuit Advertising Drives the Litigation Lifecycle*, authored by the U.S. Chamber Institute for Legal Reform, and dated April 2020.

14. Attached hereto as **Exhibit F** is a true and correct copy of the *Legal Monitor Worldwide* article "Attorneys Handling Baby Powder Lawsuits Help Families of Women Suffering from Ovarian Cancer," dated October 23, 2014.

15. Attached hereto as **Exhibit G** is a true and correct copy of the *PRWeb* article "Attorneys Provide New Case Summaries for Talcum Powder Cancer Lawsuits," dated December 16, 2014.

16. Attached hereto as **Exhibit H** is a true and correct copy of the iSpot.tv advertisement, "Dalimonte Rueb, LLP TV Commercial, 'Talcum Powder Legal Helpline: Ovarian Cancer & Mesothelioma,'" available at https://www.ispot.tv/ad/ZNKY/dalimonte-rueb-llp-talcum-powder-legal-helpline-ovarian-cancer-and-mesothelioma.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information and belief.

Dated: June 18, 2021

Kathleen Frazier

EXHIBIT A

Jury Orders J&J to Pay $72M in Ovarian Cancer Talcum Powder Case

By Michelle Llamas

Published: *February 24, 2016*

This page features

3 Cited Research Articles

FACT CHECKED

powder caused her ovarian cancer.

The St. Louis jury found J&J knew about the link between talc-based products and cancer for decades and failed to warn the public. They found the company liable for fraud, negligence and conspiracy. The jury ordered J&J to pay $10 million in compensatory damages and $62 million in punitive damages. This is the first verdict to award damages in a talcum powder case.

For decades, women used talcum powder for feminine hygiene, sprinkling it on undergarments and the vaginal area to prevent odor or extra moisture. A 2013 study published in Cancer Prevention Research showed women who used talcum powder in the groin area had up to 30 percent greater risk in developing ovarian cancer.

Plaintiff Jackie Fox died of ovarian cancer after using Johnson's baby powder and Shower to Shower for feminine hygiene for more than 35 years. She died last year at age 62.

Fox's attorney, Jere Beasley, said J&J "knew as far back as the 1980s of the risk," but still lied to the public and regulatory agencies, Reuters reported.

J&J has not stated whether it will appeal the verdict, but it stands by its product.

"We have no higher responsibility than the health and safety of consumers, and we are disappointed with the outcome of the trial," Carol Goodrich, a Johnson & Johnson spokeswoman, said in a statement. "We sympathize with the plaintiff's family but firmly believe the safety of cosmetic talc is supported by decades of scientific evidence."

The company still faces about 1,200 more lawsuits from women and their families saying J&J was aware of the risk, but did nothing to warn consumers.

Juror: It Was Clear J&J was 'Hiding Something'

allowed the jurors to reach a verdict after only four hours.

"It was really clear they were hiding something. All they had to do was put a warning label on," Smith told Bloomberg.

In this case, Fox's lawyers revealed a 1997 letter from a former J&J consultant "warning that the company's responses to the findings of nine scientific studies could end up comparing the talc industry to the cigarette industry," the National Law Journal reported.

Talc Controversy

Scientists suspected for decades that talcum powder could be linked to ovarian cancer. In the 1970s, researchers theorized that particles of talc could enter a woman's body through the vagina and make their way to the ovaries. Since then, more studies found links between talcum powder and cancer. Though, the findings are still steeped in controversy.

Still, baby powder is a multi-million dollar product, and the revenue generated is estimated at about $19 million. About 19 percent of baby powder users in the U.S. use J&J's brand. The company still sells talc-based products even after the American Cancer Society encouraged women to switch to cornstarch for use in the genital area in 1999.

Fox's award is the largest verdict to date in this type of case, but this is not the first time J&J found itself in court over its talc products.

Deane Berg used Johnson's Baby Powder and Shower to Shower powder as a feminine hygiene product from 1975 to 2007. Like Fox, she filed a lawsuit after she was diagnosed with ovarian cancer and three doctors found talc particles embedded in cancerous tissues. The jury found J&J failed to warn, but did not award compensatory damages.

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WRITTEN BY
Michelle Llamas
Senior Writer

Michelle Llamas has been writing articles and producing podcasts about drugs, medical devices and the FDA for nearly a decade. She focuses on various medical conditions, health policy, COVID-19, LGBTQ health, mental health and women's health issues. Michelle collaborates with experts, including board-certified doctors, patients and advocates, to provide trusted health information to the public. Some of her qualifications include:

- Member of American Medical Writers Association (AMWA) and former Engage Committee and Membership Committee member
- Centers for Disease Control and Prevention (CDC) Health Literacy certificates
- Original works published or cited in The Lancet, British Journal of Clinical Pharmacology and the Journal for Palliative Medicine

Drugwatch.com writers follow rigorous sourcing guidelines and cite only trustworthy sources of information, including peer-reviewed journals, court records, academic organizations, highly regarded nonprofit organizations, government reports and interviews with qualified experts. Review our editorial policy to learn more about our process for producing accurate, current and balanced content.

1. Stempel, J. (2016, February 23). J&J must pay $72 million for cancer death linked to talcum powder: lawyers. Reuters. Retrieved from https://www.reuters.com/article/us-johnson-johnson-verdict-idUSKCN0VW20A

2. Bross, T. & Feeley, J. (2016, February 22). J&J Must Pay $72 Million Over Talc Tied to Woman's Cancer. Bloomberg. Retrieved from https://www.bloomberg.com/news/articles/2016-02-23/j-j-ordered-to-pay-72-million-over-talc-tied-to-ovarian-cancer

3. Bronstad, A. (2016, February 23). $72M Verdict in Talcum Powder Case. The National Law Journal. Retrieved from https://www.law.com//nationallawjournal/almID/1202750442247/72M-Verdict-in-Talcum-Powder-Case/

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EXHIBIT B

HEALTHCARE & PHARMA

FEBRUARY 26, 2016 / 6:04 AM / UPDATED 5 YEARS AGO

Big verdict doesn't assure more wins for plaintiffs in talc-cancer cases

By Jessica Dye

NEW YORK (Reuters) - The $72 million verdict this week against Johnson & Johnson JNJ.N in a U.S. case alleging links between talc-based powder and ovarian cancer has prompted global headlines, social media buzz and calls to lawyers from would-be plaintiffs.

Exclusive: U.S. Justice Department to elevate investigations of ransomware attacks t...

A bottle of Johnson and Johnson Baby Powder is seen in a photo illustration taken in New York, February 24, 2016. REUTERS/Shannon Stapleton/Illustration

But the attention-grabbing judgment is no guarantee future plaintiffs will be able to convince juries the company's products caused their illnesses.

About 1,200 similar cases are pending, primarily in Missouri and New Jersey state courts, but the facts are different in every one.

And even in cases with similar evidence and expert testimony, juries in mass personal-injury litigation can

come to different conclusions.

While the survivors of Jacqueline Fox were awarded $72 million by a St. Louis jury Monday, jurors in a federal court action in South Dakota - the only other talc case to go to trial - found in 2013 that J&J had been negligent but declined to award damages to plaintiff Deane Berg.

Like Fox, Berg alleged her ovarian cancer was caused by her decades-long use of J&J's talc-powder products for feminine hygiene, and jurors in both cases heard testimony about studies linking talc to cancer risks.

But, unlike Fox, who passed away several months before the trial began, Berg was in remission at the time of the trial, according to court documents.

In addition to factual differences among cases, venue can affect outcomes. Some state courts are considered more plaintiff-friendly than federal courts, which have stricter rules for the admission of evidence and expert testimony, said lawyers involved in the litigation.

One juror in the Missouri case, Jerome Kendrick, said in an interview with Reuters that he and other jurors were especially swayed by testimony from plaintiffs' medical experts and

Exclusive: U.S. Justice Department to elevate investigations of ransomware attacks t...

"The problem I had is that, according to inter office documents, J&J was aware of the potential concerns," Kendrick said. "And it really looked like instead of trying to investigate, they started talking about how to combat what would eventually be a court case."

J&J has said that "decades of sound science" prove that talc is safe. The company on Tuesday issued a statement expressing sympathy for Fox's family but disagreeing with the verdict. It also said it is exploring its post-trial options.

UNDER THE RADAR

Talc litigation got its start in 2009, when Berg filed her lawsuit. The Fox lawsuit was selected by plaintiffs' lawyers as the first to go to trial in Missouri, to serve as an early bellwether of how similar cases in that venue might fare.

The litigation flew largely under the public's radar until jurors returned the award for the family of Fox, who died in October at 62. The plaintiffs said Fox used J&J Baby Powder and Shower to Shower Powder for feminine hygiene daily for 35 years before she was diagnosed three years ago with ovarian cancer.

It has resonated with the public far more than the Berg case, which "didn't get headlines because they didn't award any damages," said R. Allen Smith, a Missouri-based lawyer who represented both the Fox family and Berg.

More cases may be filed soon, and lawyers at several plaintiffs' firms who worked on the Fox case said they are investigating thousands of additional claims.

Still, the talc cases represent a relatively small portion of the tens of thousands of lawsuits J&J is facing over its many products. For instance, it is the target of more than 44,000 cases from women who say they were harmed by pelvic mesh devices made by its Ethicon unit, and more than 8,000 against its DePuy subsidiary regarding Pinnacle metal-on-metal hip systems.

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The next J&J talc trial is set for April in St. Louis, and additional trial dates have been set for later this year.

To be successful, plaintiffs must make both a general link between talc and ovarian cancer and show that J&J's products - as opposed to something else - are to blame for their cancer.

In spite of the increased interest in the litigation following the Fox verdict, attorney Danielle Mason of Beasley Allen, who was part of the team representing the Fox family at trial, said she expected J&J to fight hard to defend itself in upcoming trials. "We're in this for the long haul," she said.

Reporting by Jessica Dye; Editing by Alexia Garamfalvi and Lisa Girion

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EXHIBIT C

LIVING

I turned down $1M from Johnson & Johnson, and blew the whistle instead

By Jane Ridley

March 2, 2016 | 4:30am

Deane Berg, in 2007, suffered from hearing and hair loss as a side effect of chemotherapy treatments. Berg's daily use of talc-based products like Johnson's Baby Powder was a factor in her stage 3 ovarian cancer diagnosis.

Brian Lehmann

Deane Berg at her home in Sioux Falls, S.D.
Brian Lehmann

Cosmetics giant Johnson & Johnson was last week ordered by a Missouri jury to pay $72 million in damages to the family of a woman whose death from ovarian cancer was linked to her decades-long use of the company's talc-based Baby Powder and Shower to Shower products. Ovarian cancer survivor Deane Berg, 58, a physician's assistant from Sioux Falls, SD, believes the judgment is a great victory. Here, Berg tells The Post's ***Jane Ridley*** *her story.*

When I first noticed spotting between my periods in the fall of 2006 at the age of 49, I chalked it up to impending menopause. But my instinct as a physician's assistant told me to get a second opinion from a gynecologist after my family practitioner told me I was fine.

So, that December, I went to Sanford Medical Center in Sioux Falls for an ultrasound. The technician was chatting away happily, but suddenly went quiet. "We'll finish this up, and the nurse practitioner will come in to talk to you," she said.

I got dressed, and the NP arrived. She put her hand on my knee. "Deane, I'm afraid something is wrong," she said. "You've got a hemorrhagic ovary. We're going to have one of the doctors review it."

The next few days were a haze. I had both ovaries removed — the non-hemorrhagic one as a precaution. I was desperately upset but, after having two daughters, now ages 30 and 27, my child-bearing years were over.

But that was the least of my concerns. The results of the biopsy in January 2007 were devastating. As a health-care professional, I saw the words "bilateral carcinoma" on the pathology report, and my heart sank. I had stage 3 ovarian cancer, which had metastasized to some of my lymph nodes. The prognosis was not good, and I was facing a life expectancy of less than five years. I had a full hysterectomy within a week and prepared to undergo six months of painful chemotherapy.

Just a couple days after the surgery, I read some literature from my oncologist that included information from Gilda's Club, the foundation created by friends of the late actress Gilda Radner. To my astonishment, it said that use of talcum powder has been implicated in the development of ovarian cancer.

There was no ovarian cancer in my family. I didn't smoke. I wasn't overweight. The one risk factor that stood out was my use of talcum powder. According to the leaflet, since the early 1980s, a slew of studies showed that women who regularly used talc for feminine hygiene had higher-than-average rates of ovarian cancer. [According to the American Cancer Society, the current body of research linking talc to ovarian cancer is mixed.]

A bombshell lawsuit against Johnson & Johnson linking ovarian cancer with talcum powder threatens to upend the cosmetics industry.
Almay

Like many others, I had dusted my perineum area with baby powder as a daily routine, like brushing my teeth, ever since I was 18. I'd used both Johnson's Baby Powder and Shower to Shower, which was specifically marketed as a feminine hygiene

product. “A sprinkle a day helps keep odor away,” the ads said. “Your body perspires in more places than just under your arms.”

To my shock, there was very little on the Internet suggesting a link between talc and ovarian cancer. It was mostly confined to medical journals and had barely registered with the general public.

But that all changed last week, exactly 10 years since my surgery, with the news that the family of Alabama woman Jacqueline Fox has been awarded $72 million in damages from Johnson & Johnson after her death from ovarian cancer was linked to her prolonged use of Baby Powder and Shower to Shower, a brand that Johnson & Johnson sold in 2012 to Valeant Pharmaceuticals International.

Jurors found Johnson & Johnson liable for fraud, negligence and conspiracy after lawyers argued that the company knew about the dangers but did nothing to inform customers.

I’m so relieved that the issue is finally getting the attention it deserves. In 2013, I, too, sued Johnson & Johnson, and a federal jury found that its body powder products were a factor in my condition. Although I was surprised that the jury awarded me zero damages — South Dakota is a very conservative state, and there had to be a unanimous verdict on whether any compensation should be paid — it was never about the money. Earlier I had turned down a $1.3 million out-of-court settlement because I didn’t want to sign a confidentiality clause.

I believe that talc can cause ovarian cancer in women. Many apply it to their private parts, and talc particles travel to the ovaries through the cervix and line the uterus and fallopian tubes, resulting in toxic effects on the ovaries. In my opinion, talcum powder products should be withdrawn from the market and, until then, be clearly labeled indicating the risk.

No woman should have to go through what Mrs. Fox and I endured, along with thousands of other ovarian cancer sufferers. My life was consumed by chemotherapy and hospital visits. I had two ports put in my chest and abdomen for the IVs. Getting the chemo in my abdomen was the worst pain I’d ever experienced, even worse than childbirth. I suffered from hair loss, nausea, lack of appetite, and I would frequently throw up. I became anemic and could barely walk. Off work for sickness for six months, I couldn’t go out in public in case my immunity was compromised. Then my hearing started to go bad, a side effect of the chemotherapy. It was a living hell, but mercifully, about a year later, in 2008, I was told my cancer went into remission.

And my case paved the way for plaintiff lawyers to bring claims for hundreds of women who blame their ovarian cancer on exposure to talcum powder. As my lawyer said, I’m the equivalent of the first smokers who sued tobacco companies because of their lung cancer. The pioneers didn’t receive compensation, but the dangers and the conspiracy were finally exposed.

Now I hope the family of Mrs. Fox will be the first of many to be awarded damages. Some people think $72 million is excessive, but I don’t think so. How can you put a value on a life?

Johnson & Johnson responded in a statement: “We have no higher responsibility than the health and safety of consumers who use our products and we sympathize with Ms. Berg. At the same time, we are pleased that the jury unanimously rejected the claim that talc is defective as labeled and declined to award any damages. It is important for consumers to know that the safety of cosmetic talc is supported by decades of scientific evidence and independent peer-reviewed studies.”

FILED UNDER **CANCER**, **JOHNSON & JOHNSON**, **LAWSUITS**, **3/2/16**

EXHIBIT D

ST. LOUIS BUSINESS JOURNAL

MARCH 11-17, 2016 • VOL. 36, NO. 30 • 36 PAGES

Ranken Jordan hits goal

Lauri Tanner and the hospital meet capital funding target for expansion launch

ANGELA MUELLER, 5

OUTSIDE FORCES

ENERGY DIP COULD HURT OFFICE MARKET

Declines in the energy industry could hit home by compressing St. Louis' office market. Jim Mosby said those decreases may force more vacancies and delay new construction.

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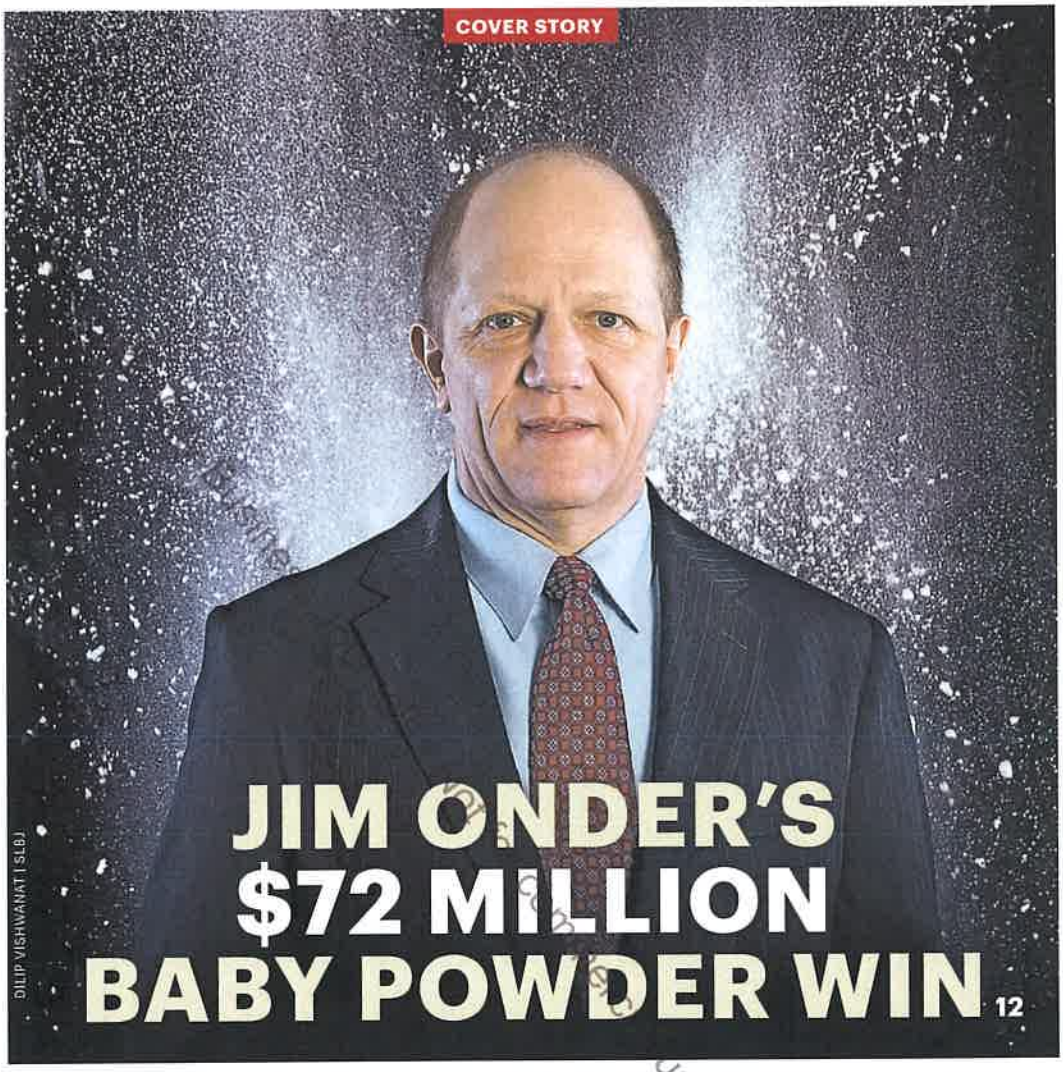

DILIP VISHWANAT | SLBJ

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$72 MILLION FOR BABY POWDER

St. Louis lawyer mines niches for riches

BY GREG EDWARDS
gedwards@bizjournals.com
314-421-8325 @stlbizgedwards

For generations, Johnson & Johnson talcum powder has been widely viewed as a benign, even beloved product, used to dust millions of baby bottoms.

St. Louis lawyer Jim Onder had always thought so, too. "Like most people, I thought talcum powder was the gentlest product, and Johnson & Johnson was a name everyone trusted."

But last month the Onder Law Firm won a $72 million verdict in St. Louis Circuit Court on a claim by the family of the late Jacqueline Fox of Birmingham, Alabama, that her longtime use of Johnson & Johnson talcum powder for personal hygiene contributed to the ovarian cancer that killed her.

It was the first jury to award damages in a case connecting talcum and cancer, and it prompted headlines around the world. Onder has gotten calls from reporters as far away as China.

In addition, his pipeline of talcum cases is overflowing, with 1,000 additional plaintiffs in St. Louis and 200 in New Jersey, as one of the lead law firms in mass tort cases. Onder works primarily with two other lawyers and their firms, Allen Smith of Jackson, Mississippi, and Ted Meadows of Montgomery, Alabama.

Johnson & Johnson is expected to appeal the verdict, which ordered the company to pay $10 million in actual damages and $62 million in punitive damages, with $31 million of that going to the Missouri Crime Victims' Compensation Fund. "We have no higher responsibility than the health and safety of consumers, and we are disappointed with the outcome of the trial," the company said in a statement. "We sympathize with the plaintiff's family but firmly believe the safety of cosmetic talc is supported by decades of scientific evidence." The company has annual revenue of $70 billion; its scores of products include Band-Aid, Listerine, Mylanta, Nicoderm and Rogaine.

Onder said he and the Fox family agreed to negotiate his firm's fee after the case has been appealed and concluded. While law firms often receive as much as a third of awards, keep in mind that the total is reduced by the $31 million to the state victims' fund.

Onder spent 15 years as a partner at Wuestling & James before starting his own firm 12 years ago. The firm, which has 50 employees, including 14 lawyers, is a jack-of-all-trades in personal injury law and has been involved in verdicts and settlement totaling $3.1 billion, including millions for birth control pills, auto collisions, medical malpractice, power line and construction accidents, faulty seat belt design and tire explosions. Each of the firm's lawyers has specialties.

The firm also has developed expertise and won millions in unusual legal niches, such as baby deaths from window cord strangulation and from the use of gels that contain benzacaine and relieve teething pain. "Most parents don't know, but if you use too much, the benzacaine can impair a body's ability to absorb oxygen," Onder said. "The baby turns blue and dies."

As for window cords, "I owned apartments with window cords, and little did I know there was a hazard," Onder said. "A baby dies at least once a month on window cords. We are the foremost international authority."

Onder, 52, said he has always been a bit of a crusader and drawn to cases that involve medicine. His brother, Missouri State Sen. Bob Onder, is a physician (he also has a law degree and a Ph.D.), and his sister, Sandra Onder Sieck, and her husband are physicians. His best friend and next-door neighbor, Scott Williams, is an obstetrician and gynecologist. "I called him and asked if this (talc) connection was real," Onder said. "He said, 'Absolutely, we learned about it in medical school 25 years ago.'"

Onder's interest in the legal industry came about at a young age.

"I take on causes," Onder said. Maybe it goes back to his childhood, growing up in St. Louis. Both of his grandmothers worked in the garment district, one in a coat factory, after their husbands died young. "We would buy our coats there for the winter," he said. "I remember as a kid seeing them in the sweat shop with 100-plus-degree heat. I saw the sweat shop first hand."

Onder took his first talcum case about three years ago. A man whose otherwise healthy wife died of ovarian cancer read about a possible connection to talc. "She had no risk factors. She was young, an exerciser, and in good health," Onder said. "When she was younger, she was a figure skater in the competition for the Olympic team." That case, Blaes v. Johnson & Johnson, is scheduled for trial July 6 in federal court in St. Louis. The cases can go to federal court if the parties are "diverse" in citizenship, generally meaning from different states.

A juror in the unanimous Fox verdict, Jerome Kendrick, said in an interview with Reuters that jurors were swayed by testimony from plaintiffs'

▸ THE JIM ONDER FILE

Age: 52

Born: St. Louis, grew up in Affton

High school: St. Louis University High School, class of 1982

College: Washington University, bachelor's degree in accounting, 1985

Law school: Saint Louis University, 1988

WINNING BIG CASES

In its 12 years, the Onder Law Firm has been involved as one of the lead law firms in cases that reaped more than $3.1 billion in verdicts and settlements, including:

- **$2 billion** paid in cases involving health problems for users of Yaz and Yasmin birth control pills.
- **$650 million** in Pradaxa settlements.

- **$71.1 million** in class actions claiming false advertising involving iTunes gift cards and Domino's Pizza delivery charges.
- **$22.5 million** for an auto collision and subsequent medical malpractice.

- **$20.5 million** for cases involving power line accidents.
- **$11.4 million** for three construction site accidents.

- **$9.9 million** for deaths and injuries resulting from tractor-trailer collisions.
- **$9.1 million** for forklift and line worker injuries.

- **$9 million** for child deaths and injuries resulting from strangulations involving mini-blind cords.
- **$8.3 million** for faulty roadway design.

- **$4.1 million** for faulty SUV back seat design.
- **$2.4 million** for defective seat belt design.
- **$2.3 million** for tire explosions.

medical experts and documents showing Johnson & Johnson employees discussing talcum powder's possible cancer risk. "It really looked like instead of trying to investigate, they started talking about how to combat what would eventually be a court case," Kendrick said.

Dr. Daniel Cramer, a Harvard epidemiologist who was an expert in the preparation of the Fox case, wrote about a potential link in 1982. Since then, 23 studies have shown a positive association, Onder said.

But the facts are different in every case, the scientific evidence is not conclusive, and jurors in a federal case in South Dakota, the only other talc case to go to trial, found in 2013 that Johnson & Johnson had been negligent but declined to award damages. And Onder doesn't take all comers. "Each case costs $5,000 to medically screen," he said.

Experts say it is possible that talc reaches the ovaries by traveling up the vagina, through the uterus and fallopian tubes and into the ovaries, causing inflammation. Dr. Adetunji Toriola, a Washington University epidemiologist at Siteman Cancer Center, told Reuters: "We know that inflammation increases ovarian cancer risk. We know that talcum powder causes inflammation. The question is, does talc cause cancer by causing inflammation in the ovaries?"

In 2016, an estimated 22,280 women will receive a new diagnosis of ovarian cancer, and about 14,240 will die from it, according to the American Cancer Society. Ovarian cancer ranks fifth in cancer deaths among women, and a woman's risk of getting it is about 1 in 75.

PERSONALLY SPEAKING ...

What is your favorite restaurant? We have no creativity. There are three we go to all the time: Kreis' on Lindbergh, the Tenderloin Room at the Chase and Cafe Napoli in Clayton.

What are you reading? I joke that I don't read anything that doesn't make me money, so mostly legal publications.

What do you like to do to relax? My hobby is real estate. My hobby is making money. I bought my first rental property on a credit card two weeks after law school. I love working.

Do you like to travel? A couple of times a year, usually to an ocean destination in Florida or California. I get invited to speak at a lot of great places, so that's nice.

What do you drive: A Maserati is my daily car, a Lamborghini is my fun car.

Tell us about your family. My wife, Maureen, and I will have been married 25 years this year. We have five kids. Our son, Jim, is a sophomore at the University of Texas business school. Michelle is a freshman at Cornell University. Maggie is a freshman at MICDS. Jack is a sixth grader at Chaminade, and Tommy is in second grade at Villa Oak Hill.

WHAT TO LOOK FOR IN TALC CASES

- Four years of continuous talcum powder use.
- Diagnosed with cancer at 65 or younger.
- Must be ovarian or fallopian tube cancer, not cervical, uterine or other cancers.
- Must be BRCA positive, a form of genetic testing.

SOURCE: THE ONDER LAW FIRM

DILIP VISHWANAT | STLBJ

Watch the behind-the-scenes video of this week's cover shoot at bizjournals.com\stlouis

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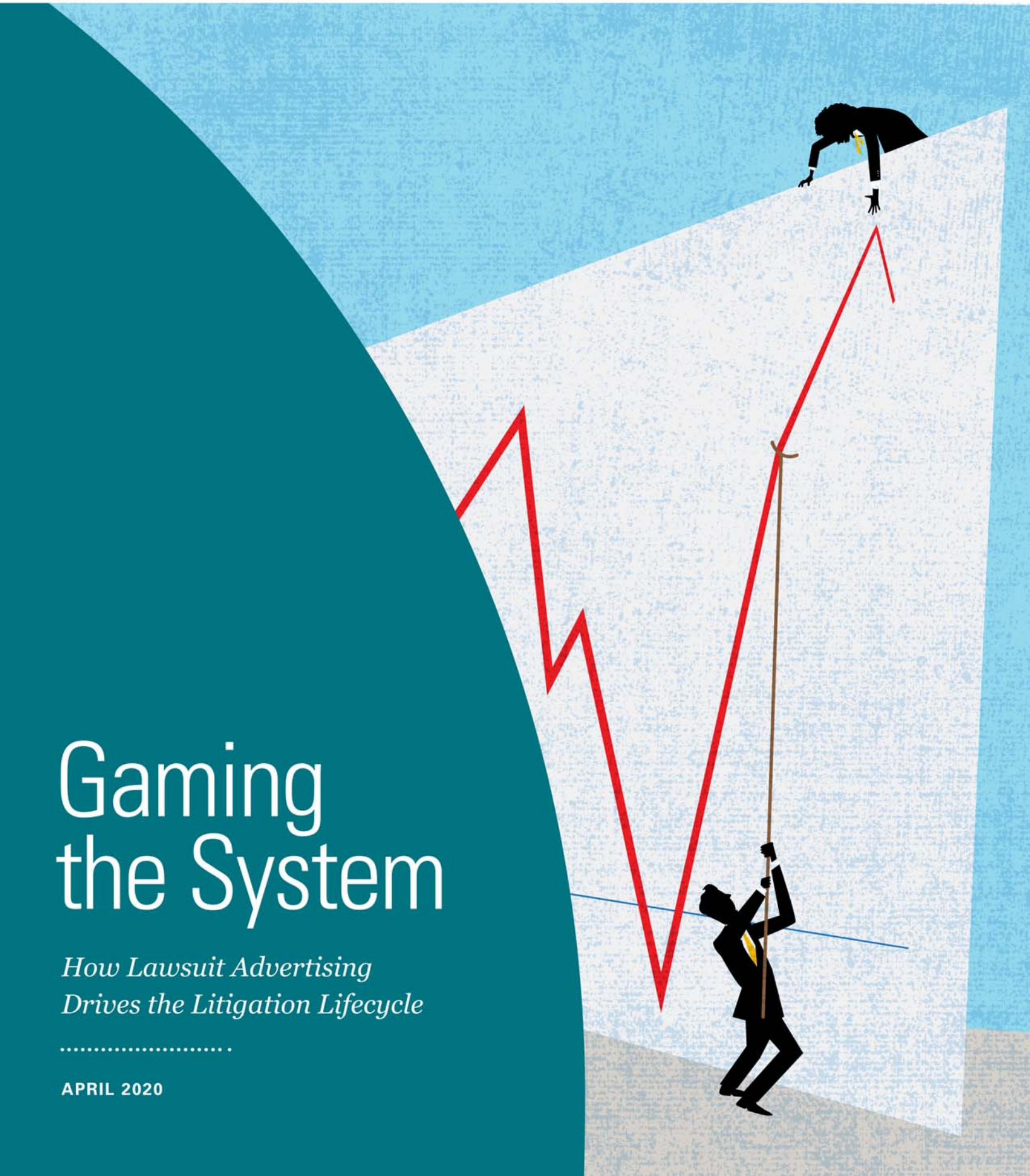

Gaming the System

How Lawsuit Advertising Drives the Litigation Lifecycle

APRIL 2020

U.S. CHAMBER
Institute for Legal Reform

An Affiliate of the U.S. Chamber of Commerce

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Prepared for the U.S. Chamber Institute for Legal Reform by

Cary Silverman, Shook, Hardy & Bacon L.L.P.

Introduction and Executive Summary

Have you taken a blood-thinning medication, used baby powder, applied weed killer, or had a medication prescribed for nausea while pregnant and experienced an injury? Call right now! For these products alone, plaintiffs' lawyers and lead generators have spent about $400 million to air 1.3 million television commercials. By comparing monthly advertising data with developments in science, regulation, and litigation, this paper identifies what sparks the ads often seen on daytime or late-night TV and explores why ads targeting a particular product surge or plummet. The proximity and likelihood of trials, the opportunity to publicize large awards, and the expectation of a global settlement drive—and are driven by—mass tort litigation advertising.

Plaintiffs' lawyers, companies that specialize in advertising and gathering claims (known as "lead generators"), and third parties that finance the litigation spend about $1 billion on television advertising each year to seek plaintiffs for mass tort litigation.[1] This paper closely examines ads seeking individuals for lawsuits involving five products: the blood-thinning drugs Pradaxa and Xarelto, talcum-based products such as baby powder, the herbicide Roundup, and the nausea-reducing medication Zofran.

The research reveals that heavy spending on lawsuit advertising does not reflect the safety of a product; rather, the ads often do not rely upon sound science, and they fluctuate from month to month based on the perceived likelihood that the litigation will yield a favorable return on the investment. Mass tort litigation is often a gamble by plaintiffs' lawyers that a business faced with thousands of claims, damage to its reputation, and rising defense costs will eventually be pressured into entering a global settlement even if the product at issue did not cause the illnesses or injuries alleged in the lawsuits.

> *While personal injury lawyers did not win a single trial, their firms will receive $105 million in fees and costs from the Xarelto litigation—a significant return on their investment.*

Pradaxa Litigation: $94 Million Spent on 289,000 Ads

The Pradaxa litigation shows how plaintiffs' lawyers take advantage of known risks of medications combined with uncertainty regarding new drugs to create a mass tort. Pradaxa, like other anticoagulants, included a risk of bleeding. After the Food and Drug Administration (FDA) announced that it was investigating such reports, plaintiffs' lawyers pounced. The 4,000 cases that resulted from the initial advertising campaign settled for $650 million before a single trial, even as the FDA found Pradaxa had no higher bleeding risk than warfarin—a medication widely used for preventing and treating blood clots in humans since the 1950s. Another wave of lawsuit ads then publicized the settlement, generating a second wave of litigation. Plaintiffs' law firms and lead generators then sharply reduced spending on advertising as juries returned defense verdicts or relatively small awards and judges dismissed cases. Ultimately, plaintiffs' lawyers have spent $94 million on 289,000 television commercials that generated over 6,000 claims. Advertising remains at low levels as the litigation continues.

Xarelto Litigation: $122 Million Spent on 375,000 Ads

Plaintiffs' lawyers applied the Pradaxa litigation playbook to a more frequently-prescribed anticoagulant, Xarelto, generating more claims. Xarelto came to market soon after Pradaxa, and plaintiffs' lawyers quickly incorporated it into Pradaxa lawsuit ads. After the Pradaxa settlement, Xarelto advertising surged. Spending increased when trial dates approached, as plaintiffs' lawyers speculated that a large award would drive up settlement values. After a series of defense verdicts, however, advertising slowed and then dried up completely. In all, plaintiffs' lawyers spent $122 million on 375,000 Xarelto television commercials, generating over 30,000 claims. The manufacturers settled for $775 million to avoid continued protracted litigation. While personal injury lawyers did not win a single trial, their firms will receive $105 million in fees and costs from the Xarelto litigation—a significant return on their investment.

Talcum Powder Litigation: $63 Million Spent on 175,000 Ads

The talcum powder litigation demonstrates how plaintiffs' lawyers can generate mass tort litigation by promoting a questionable link between a commonly used product and illnesses that thousands of people are diagnosed with each year—in this case, baby powder and ovarian cancer or mesothelioma. Cases that rely on weak science can still pressure a business to settle if it faces thousands of claims, steep defense costs, and damage to the reputation of its products and brand. Concentrating the litigation and the first trials in a court known for plaintiff-friendly verdicts and high awards can bolster the litigation's prospects. Plaintiffs face the risk, however, that judges and juries who demand reliable scientific support for claims will not respond favorably. That dynamic has occurred in the talc litigation.

Advertising began slowly after an international agency classified talc as "possibly carcinogenic" and swelled after a series of multimillion-dollar verdicts in St. Louis and Los Angeles in 2016 and 2017. It increased again after a $4.69 billion verdict, also in St. Louis, in a multi-plaintiff case in 2018. Spending on talc lawsuit advertising has fluctuated like a volatile stock, rising to publicize massive awards, and falling with dismissals, defense verdicts, invalidation of awards, and other rulings favorable to defendants. Plaintiffs' lawyers have spent about $63 million to air 175,000 talc lawsuit ads, generating 18,000 lawsuits and counting.

Roundup Litigation: $103 Million Spent on 450,000 Ads

The Roundup litigation raises questions as to whether lawsuit advertising not only generates claims but also can influence the jury pool. Litigation alleging that exposure to Roundup caused people to develop cancer, as with the talcum powder litigation, began slowly after an international agency classified its active ingredient, glyphosate, as "probably carcinogenic." Advertising remained at low levels for over three years and saw its first bump after the federal judge overseeing the litigation ruled the cases would go to trial despite shaky science. Lawsuit advertising surged as trials approached, during trials, and after plaintiffs' verdicts.

Prospective jurors reported that ads telling them Roundup causes cancer aired so frequently they were "bordering on harassment." After a $2 billion verdict to a California couple, spending on lawsuit advertising exploded to publicize the blockbuster award—and ads continued to feature the $2 billion award long after the court cut it to $86 million. This spike continued as plaintiffs' lawyers rushed to generate claims following reports of a falsely-rumored $8 billion global settlement. Thus far, plaintiffs' lawyers and lead generators have spent about $103 million to air 450,000 ads, generating nearly 50,000 claims. Although lawsuit advertising began in late 2015, three quarters of this spending occurred after the $2 billion verdict in May 2019.

Zofran Litigation: $13 Million Spent on 30,000 Ads

The Zofran litigation is an example of a failed investment by plaintiffs' lawyers. Doctors sometimes prescribe Zofran, an anti-nausea drug approved to help cancer patients during chemotherapy, to help pregnant patients experiencing severe morning sickness. Within days of publication of a Swedish study linking Zofran to birth defects, the lawsuit ads began. The first lawsuits came about three months later as ad spending exploded. Plaintiffs' lawyers and lead generators poured money into Zofran lawsuit ads, making the medication one of the most frequently targeted products in 2015. About 95 percent of the $13 million spent on Zofran lawsuit advertising occurred in just six months. Television commercials flashed images of babies, emphasized that the FDA had not approved Zofran for use by pregnant women, and highlighted a $2 billion settlement involving the drug that was unrelated to the product liability litigation.

Plaintiffs' lawyers, however, either overestimated the pool of potential plaintiffs—women who took Zofran and had a child with a birth defect—or thought each claim would result in a large verdict or settlement since the cases involve children. Nearly half of the 700 cases filed were voluntarily withdrawn by plaintiffs' lawyers or dismissed by courts, and no case has reached trial. Plaintiffs' lawyers also lost a gamble that the FDA would require labeling changes cautioning against using Zofran during pregnancy. Instead, the FDA thoroughly rejected such a request as unsupported by science, just as the litigation began to mount. As a result, plaintiffs' lawyers and lead generators pulled the plug on Zofran lawsuit advertising, which dried up as quickly as it began.

Findings: Lawsuit Advertising Trends and Public Policy Implications

There are common trends in the lifecycle of lawsuit advertising spending behavior across the five mass tort litigations examined in this report:

TRIGGERING EVENT

Mass tort advertising begins after a triggering event such as publication of a scientific study suggesting an association between a product and an illness (even if weak or flawed), the FDA's initiation of an investigation, or an organization's classification of a substance as possibly carcinogenic.

OPTIMISM-GENERATING EVENT

Advertising increases after an event suggests that the litigation is likely to reach trial and has a chance of success. These litigation benchmarks may include a court denying a motion to dismiss, scheduling cases for trial, or an early plaintiffs' verdict, even if it returns only a partial victory or a relatively small award. These types of events send a message to plaintiffs' lawyers and lead generators that the litigation is a worthy investment.

> *"Early lawsuit advertisements tend to cast a broad net for potential plaintiffs by asserting that the product may cause a wide range of illnesses."*

SURGE-GENERATING EVENT

Advertising spikes after a blockbuster award, which plaintiffs' lawyers highlight in ads to suggest that viewers who used the product may receive similar results. Rumors of a global settlement may also lead to increased advertising, as plaintiffs' lawyers attempt to generate as many claims as possible to have a piece of the settlement pie.

ADVERTISING-DEPRESSING EVENT

Plaintiffs' lawyers and lead generators typically reduce lawsuit advertising when events occur that lead them to question the soundness of their investment in the litigation. These types of developments include a court's dismissal of a claim, a jury returning a defense verdict, or an agency action finding that science does not support the claims made in the litigation.

There are also commonalities in lawsuit advertising content:

SHIFTING ASSERTIONS OF HARM

Early lawsuit advertisements tend to cast a broad net for potential plaintiffs by asserting that the product may cause a wide range of illnesses. As courts reject these claims as unsupported by science, the product risks communicated in the lawsuit ads narrow or change.

MISLEADING PRACTICES

Lawsuit ads often incorporate elements that mislead viewers. These include introducing the ad as a "medical alert," presenting the ad in a news-type format, flashing the official logo of a government agency, overstating the risks of a drug, or implying that the product has been recalled. An emerging practice is to introduce a "doctor" who explains the science purportedly supporting the litigation when that person's expertise is in a wholly unrelated field.

AWARDS PROMINENTLY FEATURED

Blockbuster awards, settlement amounts, and civil fines play a key role in lawsuit ads. Plaintiffs' lawyers and lead generators likely find that flashing multimillion-dollar figures on television is effective in motivating viewers to call. The ads do not reflect that trial and appellate court judges often throw out or substantially reduce extraordinary awards as unsupported by the evidence, excessive, or contrary to law.

Television advertisements that seek plaintiffs for mass tort litigation are intended to generate a profit for plaintiffs' lawyers and lead generators, but they also raise significant public health and due process concerns; misleading advertising practices and exaggerated assertions that a product is dangerous can cause harm. Reports filed with the FDA indicate that the lawsuit ads targeting anticoagulants scared scores of patients into stopping their prescribed medication, leading to deaths, strokes, and other serious injuries.[2] In addition, the pervasiveness of television

commercials telling viewers that consumer products, pharmaceuticals, and medical devices cause harm may poison the jury pool and jeopardize the right to an impartial jury.

Conclusion

Mass tort litigation is a profit-driven industry. In some cases, claims may seek compensation for people who were actually harmed by a defective product. However, plaintiffs' lawyers, lead generators, and third-party funders also create mass tort litigation through misleading, fearmongering ads. Through these ads, call centers, and a network of law firms, businesses are inundated with lawsuits. As cases mount, they are pressured to settle due to the cost of never-ending litigation, the risk of liability (particularly in areas viewed as plaintiff-friendly), and damage to their reputations.

Spending on lawsuit advertising rises and falls primarily based on the perceived likelihood that a defendant will enter a global settlement that will yield a return on the investment. While attorney advertising is protected by the First Amendment, legislators and regulators can and should step in when ads mislead the public or jeopardize public health. Courts also need to protect the right to a fair trial by ensuring prospective jurors—besieged with ads sponsored by plaintiffs' lawyers telling them a product is harmful—can impartially consider the evidence.

Data Sources

The advertising data presented in this paper was provided by Kantar CMAG. For each litigation examined in this paper, Kantar CMAG estimated the amount spent on lawsuit advertising and the number of advertising spots that ran from the outset of the litigation to its conclusion or through December 2019. Kantar CMAG monitors 210 media markets, 11 national broadcast networks, and more than 80 national cable networks.

This paper does not reflect the full extent of money spent on lawsuit advertising and shows just a small piece of the lawsuit-generating industry. The television advertising data does not include local cable advertising, which Kantar CMAG does not monitor. Nor does this paper attempt to estimate the amount spent on lawsuit advertising in print media, internet, or social media ads, which is substantial.

The paper also presents the number of lawsuits pending for each litigation. This data is drawn from the Judicial Panel on Multidistrict Litigation, which publishes federal court statistics on a monthly basis. Data on state court filings, or all U.S. plaintiffs, is drawn from company quarterly or annual reports or, when not available, from media reports or other public sources.[3]

"Spending on lawsuit advertising rises and falls primarily based on the perceived likelihood that a defendant will enter a global settlement that will yield a return on the investment."

Case Study: Pradaxa Litigation

Plaintiffs' law firms and lead generators spent an estimated $94 million to air roughly 289,000 television commercials telling viewers that a new blood thinning medication, Pradaxa, can result in serious internal bleeding and death. An initial advertising campaign took advantage of unfamiliarity and uncertainty with the new drug soon after it came to market. After the manufacturer settled the first surge of lawsuits before any case reached trial, plaintiffs' lawyers advertised the settlement to generate a second wave of litigation. Meanwhile, the FDA reaffirmed Pradaxa's safety and most judges and juries have found for the defendants.

About Pradaxa

Dabigatran (marketed as Pradaxa) was the first in a new class of anticoagulants known as a direct thrombin inhibitor. The FDA approved Pradaxa in 2010 for reducing the risk of stroke and systemic embolism in patients with atrial fibrillation (an irregular heartbeat) not caused by a heart valve problem.[4] The medication reduces the risk of clots that are a leading cause of atrial fibrillation-related strokes. Pradaxa is also approved to treat patients who have blood clots in the veins of their legs (deep vein thrombosis) and lungs (pulmonary embolism). It is used to treat and reduce the risk of reoccurrence of thrombosis after hip replacement surgery. As with all blood-thinning medications, doctors and their patients know there is a risk of the drug resulting in serious bleeding.[5] The drug's safety information informs patients that it is important for them to take it as instructed by their doctor, because stopping the medication can increase the risk of a stroke.

Until Pradaxa, patients who needed blood-thinning medication generally relied on warfarin, which had drawbacks such as the potential to interact with food and other medications, and the need for frequent monitoring and dose adjustment.[6]

Pradaxa is made by Boehringer Ingelheim, a family-owned company established in 1885 that is located in Germany and has its U.S. headquarters in Connecticut.

Public Health and Safety Assessments

Approximately one year after Pradaxa's approval, the FDA announced that it had received reports of "serious bleeding events" in patients taking Pradaxa.[7] The agency indicated in December 2011 that it would investigate these reports but cautioned that the "FDA continues to believe that Pradaxa provides an important health benefit when used as directed" and that patients should not stop taking their prescribed medication without consulting with their doctor.[8] These concerns were amplified when, one month later, a study published in the *Archives of Internal Medicine* associated Pradaxa with an increased risk of heart attack compared to other anticoagulants.[9]

In November 2012, the FDA indicated that it had evaluated these reports and "not changed its recommendations regarding Pradaxa," recognizing the medication provides an important health benefit in reducing the risk of stroke and blood clots when used as directed.[10] The FDA found that "a simple comparison between Pradaxa and warfarin with respect to the numbers of post-marketing reports of bleeding ... is misleading because bleeding events associated with warfarin (a well-recognized consequence of warfarin use, which has been available for many years) are likely underreported compared to events occurring with the more recently available Pradaxa."[11] "[B]leeding rates associated with new use of Pradaxa do not appear to be higher than bleeding rates associated with new use of warfarin," the agency concluded.[12]

The FDA's evaluation of Pradaxa continued and, in May 2014, the agency announced that it had completed a new study of more than 134,000 patients and found that Pradaxa is generally safer than warfarin.[13] The FDA compared Pradaxa to warfarin for risk of ischemic or clot-related stroke, bleeding in the brain, major gastrointestinal (GI) bleeding, myocardial infarction (MI), and death.[14] It concluded that Pradaxa was associated with a lower risk of clot-related strokes, bleeding in the brain, and death than warfarin.[15] The MI risk was similar for the two drugs.[16] The study did find an increased risk of major gastrointestinal bleeding with taking Pradaxa as compared to warfarin.[17] After reviewing these findings, the agency indicated that "we still consider Pradaxa to have a favorable benefit to risk profile and have made no changes to the current label or recommendations for use."[18]

Some raised concerns that Pradaxa lacked a "reversal agent" that can be administered when a patient taking the medication needs emergency surgery or experiences uncontrolled bleeding. The FDA responded, however, that "the lack of an antidote notwithstanding, [Pradaxa] was superior to

"After reviewing these findings, the agency indicated that 'we still consider Pradaxa to have a favorable benefit to risk profile and have made no changes to the current label or recommendations for use.'"

> *"As the federal MDL concluded in mid-2015, plaintiffs' lawyers initiated a 'second wave' of Pradaxa litigation, largely in state courts."*

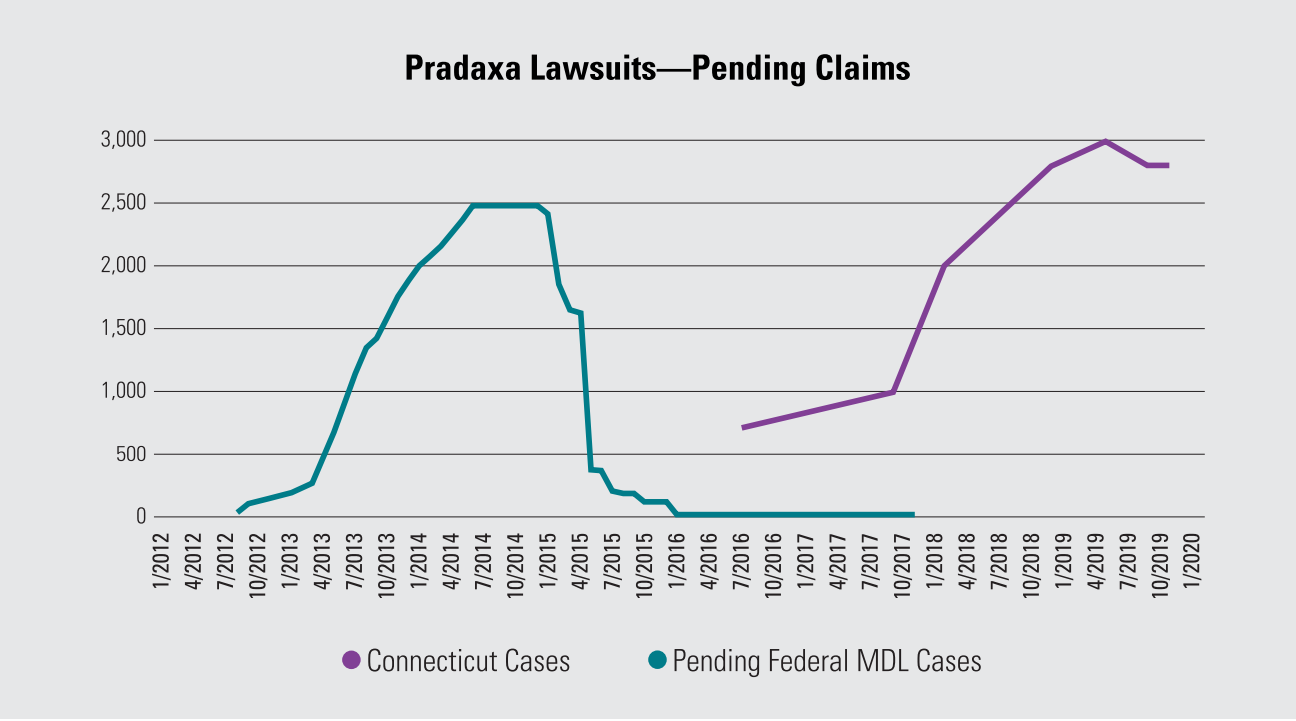
warfarin in preventing strokes in a large clinical trial [and] the rates of bleeding were similar."[19] In October 2015, the FDA granted accelerated approval to Praxbind, a specific reversal agent for Pradaxa.[20] After completing its review of Praxbind's safety, the FDA announced full approval in April 2018.[21]

An Overview of the Litigation

The Pradaxa litigation is unique in having two phases: (1) litigation in federal courts that largely ended following a settlement; and (2) litigation, primarily in certain state courts, that only started to pick up following that settlement.

Plaintiffs' lawyers filed the first reported lawsuits alleging injuries from Pradaxa use in early 2012, soon after the FDA's announcement of its investigation and publication of the *Archives of Internal Medicine* article.

In August 2012, the U.S. Judicial Panel on Multidistrict Litigation (MDL) established a proceeding for all federal actions alleging that plaintiffs suffered severe bleeding or other injuries as a result of taking Pradaxa, that the manufacturer did not adequately warn prescribing physicians of the risks associated with the medication, or that there is no reversal agent to counteract Pradaxa's anticoagulation effects.[22] Twenty-one Pradaxa cases then in federal courts, as



well as future cases, were centralized in the U.S. District Court for the Southern District of Illinois for pretrial purposes.[23] The court set four bellwether trials for late 2014 and early 2015.[24]

The MDL quickly grew. Within one year of its establishment, there were over 1,000 pending claims.[25] Lawsuits continued to mount as the judge presiding over the MDL, U.S. District Judge David R. Herndon, denied the first motion to dismiss a plaintiff's failure to warn claims in July 2013[26] and hit the company with a nearly $1 million sanction for failing to produce documents sought in discovery in December 2013.[27] Pending claims in the MDL reached 2,000 within 18 months.[28]

Claims in the MDL peaked at about 2,500 in mid-2014,[29] coinciding with the May 2014 announcement of a $650 million settlement that included the MDL claims, plus about 1,500 cases filed in state courts in Connecticut, California, Illinois, and Delaware.[30] Pending claims in the MDL remained flat for several months, then began to decline in January 2015 as individual cases were dismissed as a result of the settlement. No case in the federal MDL reached a trial.

As the federal MDL concluded in mid-2015, plaintiffs' lawyers initiated a "second wave" of Pradaxa litigation, largely in state courts.[31] These new lawsuits were primarily filed in Connecticut, where the company's U.S. headquarters are located. By February 2018, 2,000 claims were pending in coordinated litigation, a state proceeding that is similar to a federal MDL, in the Connecticut Superior Court.[32]

The first three Pradaxa cases to go to trial ended in defense verdicts in 2018. In the first two cases, Connecticut juries found that the plaintiffs' injuries were not caused by the medication, even if the company should have provided stronger warnings of the risk of bleeding or further researched the drug.[33] The third trial resulted in a full defense verdict.[34]

Plaintiffs obtained their first win in a Pradaxa case later in a federal court in West Virginia in October 2018—a $1.25 million verdict.[35] A second plaintiff's verdict occurred in Connecticut in May 2019.[36] That verdict included $542,000 in compensatory damages and a finding that punitive damages were warranted (under Connecticut law, a judge decides the amount of punitive damages). In September 2019, Judge Carl Schuman, who presides over Connecticut's Pradaxa litigation, found "at least minimally sufficient evidence" to support the verdict.[37] He awarded just $1 in punitive damages, however, noting that "[t]his case is not one in which a company, motivated by greed, proceeded to ignore

> *"The court found the plaintiff did not present persuasive evidence showing the manufacturer had discovered any significant new information about the drug that would have allowed it to alter the drug's label."*

safety standards, defy government regulations, or disregard scientific literature in order to put an unreasonably dangerous or socially worthless product on the market."[38] The court's detailed ruling suggests that Judge Schuman is likely to dismiss other plaintiffs' claims that the company should have warned doctors to monitor the level of Pradaxa in their patients' blood as preempted by federal law. While the court upheld the verdict due to that plaintiff's particular condition and uncommon claim, observers say that Judge Schuman's thorough analysis of the science and FDA regulations may doom most of the 2,800 remaining Pradaxa cases in Connecticut.[39] As predicted, Judge Schuman dismissed another case as preempted by federal law on March 13, 2020.[40]

Meanwhile, a California state court judge dismissed a Pradaxa case in January 2019, after the plaintiff's own doctor indicated in a deposition that additional risk information he was shown about Pradaxa would not have changed his decision to prescribe the drug to his patient.[41] The judge also tossed 141 out-of-state suits from the California consolidated proceedings, finding they lacked a sufficient connection to the state.[42] Another plaintiffs' defeat occurred in California in November 2019, when a state court judge ruled that federal law preempts claims that the pharmaceutical company should have provided additional warnings regarding the blood thinner's internal bleeding risks.[43] The court found the plaintiff did not present persuasive evidence showing the manufacturer had discovered any significant new information about the drug that would have allowed it to alter the drug's label.[44]

Lawsuit Advertising Messaging

Television advertisements seeking to recruit plaintiffs for Pradaxa lawsuits are often presented as a "medical alert" or "drug alert." They tell viewers that Pradaxa is linked to serious internal bleeding, which can result in hemorrhaging, stroke, or "even death." Some ads tell viewers that if they are one of the millions of Americans taking Pradaxa, "you could be at serious risk." Some ads caution that viewers should not stop taking their medication without consulting with a doctor, but many do not. Many ads do not identify the law firm that is responsible for the ad, but rather run under banners such as "injury help desk" and "legal helpline."

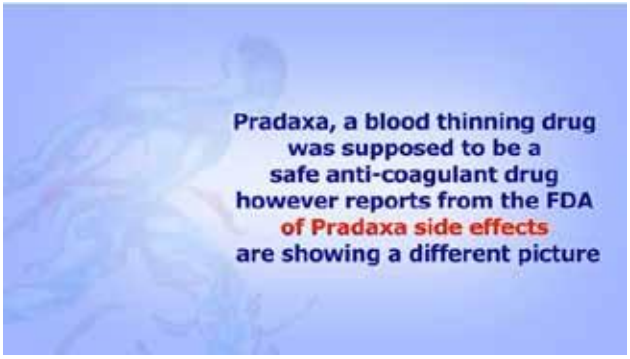
Early ads emphasized the FDA investigation of reports of internal bleeding associated with Pradaxa. One 2012 online ad, for example, flashes the FDA logo and tells viewers that Pradaxa has been linked to "bleeding on the brain, intestinal bleeding,

> *"According to data compiled by Kantar CMAG, law firms and lead generators spent an estimated $94 million to air about 289,000 Pradaxa lawsuit ads between 2012 and 2019."*

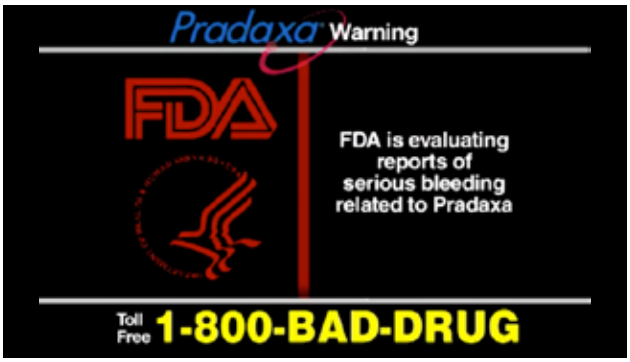
kidney bleeding, uncontrolled bleeding, or even death." In fine print below, that ad informs viewers that Pradaxa has not been recalled by the FDA. Other ads state that concerns about Pradaxa were raised almost as soon as it arrived on the market, assert that it has caused hundreds of deaths, or emphasize that it lacks an antidote.

After 2015, plaintiffs' lawyers and lead generators often aired advertisements targeting both Pradaxa and Xarelto. Many of the lawsuit ads seeking to generate a second wave of litigation emphasize the $650 million Pradaxa settlement.

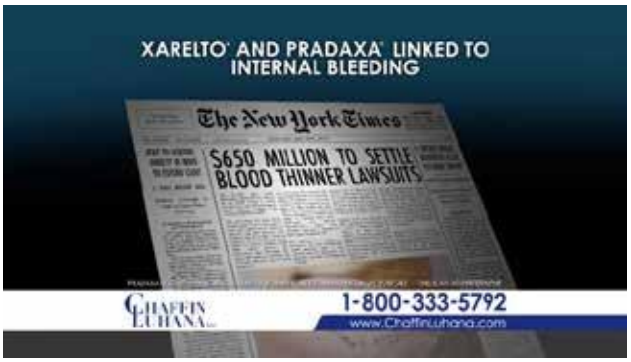
FaultyDrugs.com, "Pradaxa Lawsuit," YouTube, posted Mar. 1, 2012.



PradaxaLawsuitSettlements.com, "Pradaxa Lawsuit Join Now," YouTube, posted Sep. 21, 2012.



1-800-BAD-DRUG, "Pradaxa Internal Bleeding Lawsuits," YouTube, posted Jan. 31, 2013.



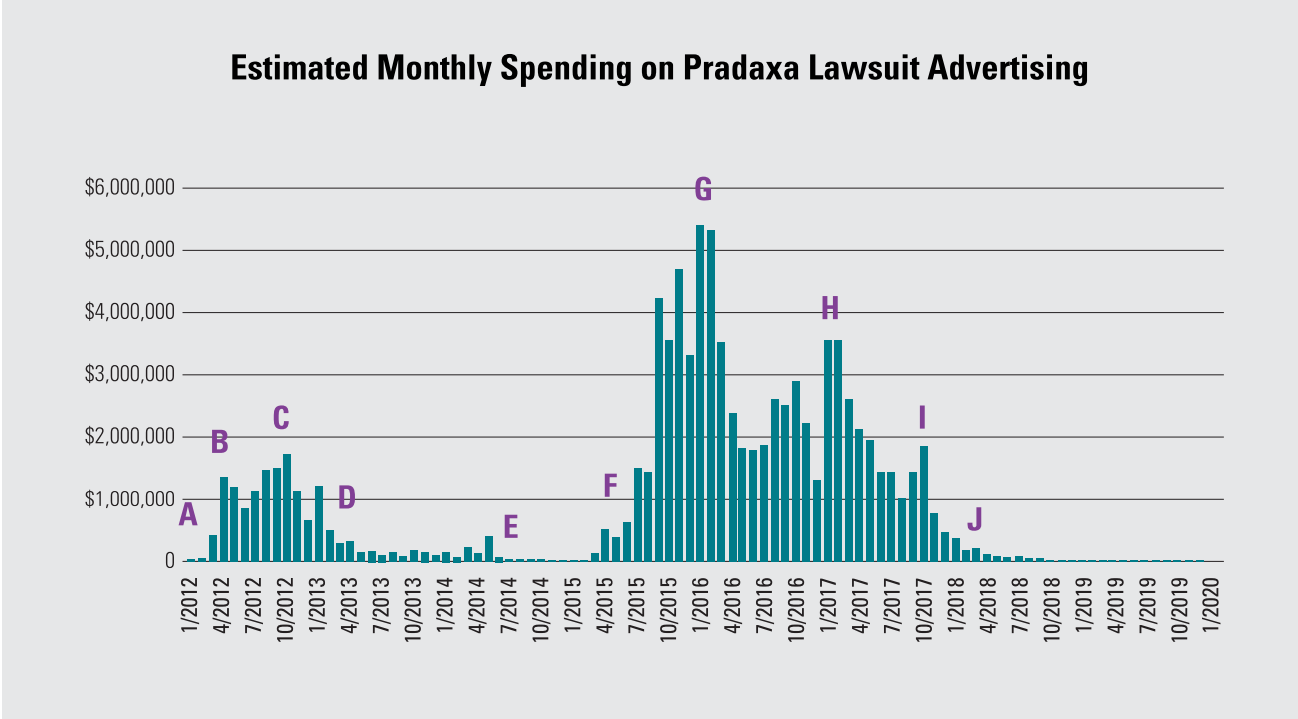
Chaffin Luhana LLP, "Xarelto or Pradaxa Defective Drug Recall," YouTube, posted Oct. 6, 2015.

The Sentinel Group TV Commercial, "Xarelto & Pradaxa Alert," iSpot.tv, aired 2015.

Injury Help Desk TV Commercial, "Xarelto/Pradaxa," iSpot.tv, aired 2016.

Goldwater Law Firm TV Commercial, "Xarelto and Pradaxa Settlements," iSpot.tv, aired 2016-17.

Xarelto & Pradaxa Legal Helpline TV Commercial, "Serious Risk," iSpot.tv, aired 2017.



Spending on Lawsuit Advertisements

According to data compiled by Kantar CMAG, law firms and lead generators spent an estimated $94 million to air about 289,000 Pradaxa lawsuit ads between 2012 and 2019. More than 80 percent of this spending occurred between 2015 (after the initial settlement) and 2017 (before a string of defense verdicts).

Certain advertising trends vis-à-vis the Pradaxa litigation lifecycle are worthy of note (with letters corresponding to the chart above):

BENCHMARK A

Television ads recruiting plaintiffs for Pradaxa lawsuits begin soon after the FDA announces in December 2011 that it is investigating reports of severe bleeding events in patients taking the medication, and grow in frequency after a study is

published in February 2012 associating Pradaxa with a higher risk of heart attack than other anticoagulants. The first reported Pradaxa lawsuits are filed.

BENCHMARK B

By April 2012, Pradaxa lawsuit advertising surges to over 4,500 spots at an estimated cost of $1.4 million. These ads emphasize the FDA investigation, adverse event reports, early studies, and lack of a reversal agent.

BENCHMARK C

Plaintiffs' lawyers spend about $4.7 million to air nearly 14,000 Pradaxa lawsuit ads in the three-month period of August through October 2012. The federal judiciary's establishment of an MDL for Pradaxa litigation on August 8 may have contributed to this spike.

BENCHMARK D

Ad spending dives in 2013 following the FDA's announcement that Pradaxa does not have a higher bleeding risk than warfarin.

BENCHMARK E

Ad spending drops again after the FDA announces in May 2014 that a new study shows Pradaxa has a lower risk of strokes, bleeding in the brain, and death than warfarin. Two weeks later, the parties announce a $650 million settlement of 4,000 federal and state claims. In the nine months that follow, monthly ad spending does not exceed $100,000 in a single month and totals just $172,650.

BENCHMARK F

Lawsuit advertising again begins to rise in early 2015 as a "second wave" of Pradaxa litigation begins. As the MDL winds down, ad spots increase by 22 times (from 37 to 806) and spending rises by 425 times (from $1,230 to $522,980) between February and April 2015. By July 2015, lawsuit ad spending tops $1.5 million. Some ads emphasize the $650 million settlement.

"Lawsuit advertising again begins to rise in early 2015 as a 'second wave' of Pradaxa litigation begins."

BENCHMARK G

Spending on Pradaxa lawsuit advertisements peaks in early 2016 to generate more claims for the second round of litigation. Plaintiffs' lawyers spend $10.7 million to run nearly 20,000 ads in January and February 2016 alone.

BENCHMARK H

Another advertising surge occurs between January and March 2017, as plaintiffs' lawyers spend nearly $10 million to run 33,000 ads.

BENCHMARK I

After a dip in spending, plaintiffs' lawyers spend $1.8 million to air over 2,500 ads in October 2017. This occurs when the prospect of trials in Connecticut heightens as the judge overseeing the litigation finds on October 2 that whether a plaintiff filed within the three-year statute of limitations is an issue that must be decided by a jury.

BENCHMARK J

After the first defense verdict in March 2018, spending on Pradaxa lawsuit ads drops below $100,000 and continues on a downward trend. The next two trials in May and October reach the same result. Two relatively small plaintiffs' verdicts in October 2018 and May 2019 do not impact ad spending. In 2019, California courts dismiss two cases and a Connecticut court ruling suggests that the remaining cases in that state are likely to be dismissed.

Analysis

The Pradaxa litigation provides a classic example of how plaintiffs' lawyers and lead generators can use the understood risks of a drug (here, the risk of bleeding from an anticoagulant) and uncertainty regarding and unfamiliarity with a new medication to create mass tort litigation.

Advertising began as soon as concerns arose with the new drug, even as the FDA investigated and found Pradaxa's risks generally comparable to or safer than warfarin. The initial ads succeeded in generating about 4,000 claims by plaintiffs who alleged they had taken Pradaxa and experienced bleeding, a known risk. The cost of litigation and liability exposure led the company to settle the litigation for $650 million despite the lack of a single plaintiffs' verdict at that point and the FDA's reaffirming the drug's safety. About $200 million to $250 million of this sum (30 to 40 percent) likely went to plaintiffs' lawyers for their fees and expenses, allowing them to make a profit on their investment in the litigation.

Rather than end the litigation as intended, the settlement sparked another wave of lawsuit advertising and claims. Spending on advertising rose to generate more claims by highlighting the multimillion-dollar settlement and increased as trials in state courts approached.

Plaintiffs' law firms and lead generators sharply reduced advertising, however, as juries and judges repeatedly sided with defendants, and the two cases that ended in questionable plaintiffs' verdicts resulted in relatively low awards.

"The Pradaxa litigation provides a classic example of how plaintiffs' lawyers and lead generators can use the understood risks of a drug (here, the risk of bleeding from an anticoagulant) and uncertainty regarding and unfamiliarity with a new medication to create mass tort litigation."

Case Study: Xarelto Litigation

Plaintiffs' law firms and lead generators spent an estimated $122 million to air approximately 375,000 television commercials telling viewers that Xarelto can result in serious internal bleeding and death. They followed the same general playbook as the Pradaxa litigation, but this time applied it to a more frequently prescribed medication. Data suggests that plaintiffs' lawyers heavily advertised to generate as many claims as possible, taking advantage of uncertainty regarding the new drug's safety. Advertising slowed as judges and juries found that that the companies properly warned doctors of the risks of the blood-thinning medication. Despite the lack of success in court, these ads generated over 30,000 lawsuits. The growing number of lawsuits led the companies to settle, allowing personal injury law firms to recoup their investment, even as their ads scared some patients into not taking their prescribed medication.

About Xarelto

Rivaraxaban (marketed as Xarelto) followed Pradaxa as a new type of anticoagulant. The FDA first approved this blood-thinning medication in 2011. Xarelto is approved to help reduce the risk of blood clots in common conditions such as atrial fibrillation, deep vein thrombosis, and pulmonary embolism. The FDA later approved Xarelto for treating coronary artery disease and peripheral artery disease, and for preventing blood clots in acutely ill patients who are at risk for thromboembolic complications.[45] Bayer AG developed Xarelto and the medication is marketed by Johnson & Johnson (J&J) unit Janssen Pharmaceuticals, Inc.

Like other newer blood-thinning drugs, Xarelto has advantages over the long-used warfarin: Xarelto does not require regular

“In response, the FDA investigated, found the faulty device did not affect the results, and reaffirmed that Xarelto is a safe and effective treatment for patients with atrial fibrillation.”

blood test monitoring, does not affect what a patient can eat, and generally does not interact with other medications.[46]

As with all blood-thinning medications, doctors and their patients know there is a risk that taking the drug can result in serious bleeding. The medication carries a prominent “black box” warning[47] on its label informing patients that discontinuing the use of any anticoagulant increases the risk of serious blood clots and stroke and, if patients decide to stop taking it, that it may be necessary to switch to an alternative medication. In March 2014, the FDA added a black box warning advising doctors that patients having spinal procedures, such as spinal injections or epidurals, should avoid the drug.[48]

Public Health and Safety Assessments

Like Pradaxa, safety concerns arose with Xarelto soon after it became available. These concerns likely stemmed from unfamiliarity with the new blood-thinning drug and less available data compared to warfarin, which doctors had prescribed for decades.[49] The manufacturer emphasized that scientific evidence indicated that patients taking Xarelto had less risk of experiencing some of the most severe side effects than patients taking warfarin.[50]

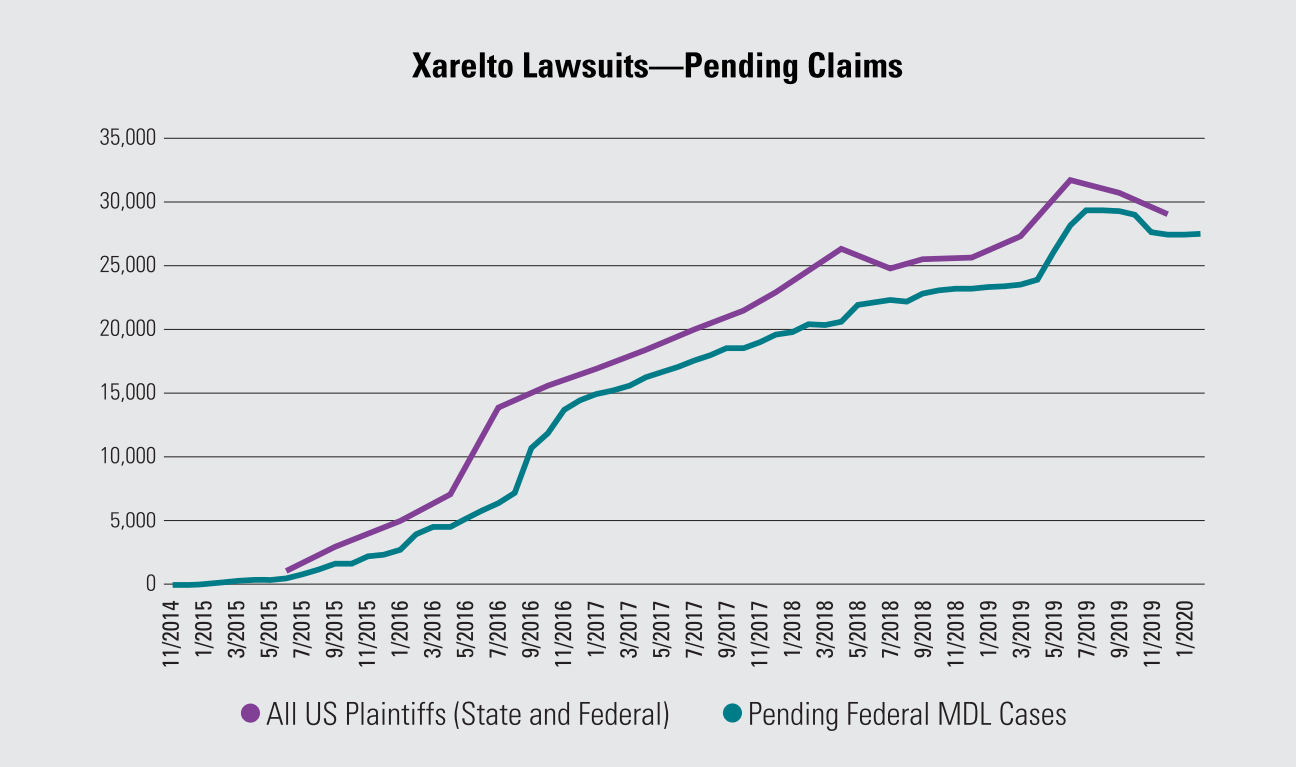
While the FDA has repeatedly expanded the approved uses for Xarelto, in several instances, advisory panels or the agency itself sought more clinical trial data before doing so.[51] The FDA’s initial rejection of these applications may have contributed to safety concerns.

There was also alarm in July 2016, when the FDA recalled a monitoring device that was used in clinical trials of Xarelto and provided data to support the FDA’s approval of the drug. In response, the FDA investigated, found the faulty device did not affect the results, and reaffirmed that Xarelto is a safe and effective treatment for patients with atrial fibrillation.[52]

An Overview of the Litigation

Over 30,000 lawsuits have been filed on behalf of individuals who allege that internal bleeding or other injuries they experienced while taking Xarelto stemmed from a failure to adequately warn of the medication’s risks.[53]

Plaintiffs’ lawyers appear to have filed the first Xarelto lawsuits by early 2014.[54] At that point, there were already about 2,000 lawsuits targeting the competing anticoagulant, Pradaxa, also discussed in this report. Plaintiffs’ lawyers claimed Xarelto had similar safety issues.



Most Xarelto lawsuits are pending in a federal MDL in the Eastern District of Louisiana, a proceeding that began with the transfer of 21 pending cases in December 2014.[55] The Philadelphia Court of Common Pleas also hosts significant Xarelto litigation, having established a mass tort program for these cases in January 2015.[56] In addition, California has a coordinated proceeding for Xarelto claims in Los Angeles.[57]

The number of Xarelto lawsuits increased exponentially in 2015 and 2016. The first thousand lawsuits were filed within months of the establishment of the federal MDL. By January 2016, there were about 5,000 lawsuits pending.[58] Within one year, that figure had tripled.[59] The number of lawsuits steadily climbed through 2018 and the first half of 2019.

> *"The number of Xarelto lawsuits increased exponentially in 2015 and 2016. The first thousand lawsuits were filed within months of the establishment of the federal MDL. By January 2016, there were about 5,000 lawsuits pending. [...] Juries have overwhelmingly found that the manufacturers properly instructed doctors on how to safely use Xarelto and about the risks involved."*

> *"Some later ads flash the $27.8 million Philadelphia verdict, which, as noted, was almost immediately thrown out by the court as contrary to the evidence."*

Juries have overwhelmingly found that the manufacturers properly instructed doctors on how to safely use Xarelto and about the risks involved. Trials began in 2017. That year, each of the three bellwether trials in federal court concluded in a defense verdict in May,[60] June,[61] and August.[62]

Xarelto lawsuits did not fare much better in state court. Plaintiffs' lawyers scored a fleeting victory in late 2017 with a $27.8 million verdict in the first case to go to trial in Philadelphia.[63] Soon after, the court threw out the verdict because the Indiana plaintiff's own doctor had testified that additional warnings would not have changed her decision to prescribe Xarelto to her patient.[64] The next two Xarelto cases to go to trial in Philadelphia ended in defense verdicts in April[65] and August 2018.[66]

After six straight victories, J&J and Bayer agreed to settle the litigation to the surprise of some observers who viewed the lawsuits as proven to be meritless.[67] The $775 million agreement, announced in March and finalized in May 2019, generally settles the claims pending at the time (at an average of about $30,000 per plaintiff before subtraction of attorneys' fees and costs).[68] Following announcement of the settlement, the number of pending Xarelto claims spiked, likely indicating that plaintiffs' lawyers are in the process of filing their remaining inventory of cases. As individual cases settle, the number of pending lawsuits is gradually declining.

Lawsuit Advertising Messaging

Television commercials typically began with an announcer telling viewers in a dire tone that the ad was a "Xarelto Alert," a "Xarelto Warning," a "Medical Alert," or an "important medical announcement." Lawsuit ads told viewers that Xarelto has been linked to "uncontrolled bleeding and death." Some ads went further, asserting that Xarelto caused bleeding of the brain or gastrointestinal system. Other ads stated that Xarelto may cause stroke, pulmonary embolism, and deep vein thrombosis–the very conditions against which doctors prescribe the blood thinner.

As shown in the Pradaxa section of this paper, television commercials targeted patients using Xarelto and Pradaxa, emphasizing the $650 million settlement in the Pradaxa litigation. Some later ads flashed the $27.8 million Philadelphia verdict, which, as noted, was almost immediately thrown out by the court as contrary to the evidence.

Norris Injury Lawyers TV Commercial, "Xarelto," iSpot.tv, last aired Nov. 14, 2014.

Xarelto Alert Helpline TV Commercial, "Serious Bleeding," iSpot.tv, last aired Jan. 19, 2015.

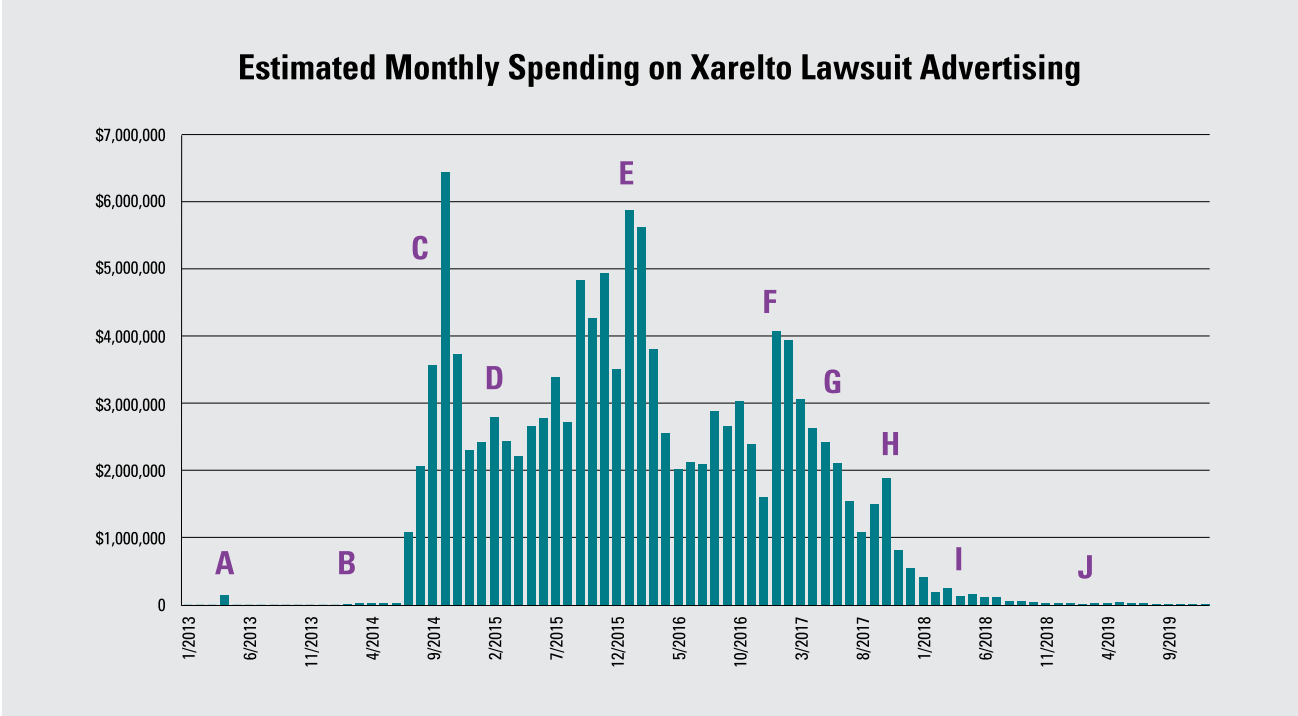
Xarelto Alert Helpline TV Commercial, "Xarelto Warning," iSpot.tv, last aired Nov. 4, 2015.

Xarelto Help Now TV Commercial, "Medical Announcement," iSpot.tv, last aired Jan. 31, 2016.

Goldwater Law Firm TV Commercial, "Xarelto and Pradaxa Settlements," iSpot.tv, aired 2016-17.

Goldwater Law Firm TV Commercial, "Xarelto Warning," iSpot.tv, last aired Jun. 7, 2018.

Law Offices of Gordon & Doner TV Commercial, "Xarelto Legal Helpline," iSpot.tv, last aired Dec. 10, 2018.



Spending on Lawsuit Advertisements

According to data compiled by Kantar CMAG, plaintiffs' law firms and lead generators spent an estimated $122 million to air about 375,000 Xarelto lawsuit ads between 2014 and 2019. Most of this spending was concentrated between mid-2014 and 2017.

BENCHMARK A

The first Xarelto lawsuit ads (217 spots at a cost of approximately $135,000) air in April 2013, less than two years after the FDA first approved Xarelto. The ad spending comes as reports linking Xarelto to adverse events are submitted to the agency and the FDA delays a requested expansion of its approval of the blood thinner to treat patients with acute coronary syndrome.

BENCHMARK B
The first reported Xarelto lawsuit in the Philadelphia Court of Common Pleas is filed by a Kentucky plaintiff in February 2014. During this month, lawsuit ads slowly resume as the FDA again denies expansion of its approval of Xarelto to include treatment of acute coronary syndrome.

BENCHMARK C
The first advertising surge begins in July 2014 and peaks at over 10,000 ads at an estimated cost of $6.5 million in October 2014. This advertising surge follows a $650 million settlement of Pradaxa litigation.

BENCHMARK D
As cases begin to mount, the federal judiciary establishes an MDL proceeding, and plaintiffs' lawyers petition the Philadelphia Court of Common Pleas to create a mass tort program. Plaintiffs' law firms and lead generators spend between $2 million and $3.5 million per month on advertising in the months that follow.

BENCHMARK E
A second advertising surge begins in September 2015 and peaks between January and March 2016. This advertising spree begins as the MDL judge sets dates for the first four bellwether trials. Spending reaches nearly $6 million in both January and February 2016, and ad spots top 16,000 in March 2016, its highest level in the litigation.

BENCHMARK F
A third advertising spike occurs between January and March 2017. During that three-month period, plaintiffs' lawyers air over 41,000 ads at an estimated cost of $11 million. These ads run as the first federal bellwether trial approaches in April 2017.

BENCHMARK G
Xarelto lawsuit advertising slows as federal trials end in three consecutive defense verdicts in May, June, and August 2017.

BENCHMARK H
The final advertising peak and last substantial month of spending on lawsuit advertising occur in September and October 2017. These ads air in the two months leading up to the first Pennsylvania trial.

BENCHMARK I
Xarelto lawsuit advertising virtually ends as the sole plaintiffs' verdict is thrown out in January 2018 and other Philadelphia trials result in defense verdicts in April and August 2018. Ad spending drops below $100,000 in July 2018 and $50,000 in October 2018.

"A third advertising spike occurs between January and March 2017. During that three-month period, plaintiffs' lawyers air over 41,000 ads at an estimated cost of $11 million. These ads run as the first federal bellwether trial approaches in April 2017."

> *"Though they did not prevail in a single Xarelto case, plaintiffs' lawyers will pocket up to $93 million in fees and $23 million in costs from the settlement."*

BENCHMARK J
A $775 million settlement is announced on March 25, 2019 and finalized in May 2019.

Analysis

The Xarelto litigation, like the Pradaxa litigation, provides an example of how plaintiffs' lawyers and lead generators can use understood risks of a drug and uncertainty regarding the safety of a new medication to create mass tort litigation. Plaintiffs' lawyers employed the same playbook for the Xarelto lawsuits as in the Pradaxa litigation, but they targeted a far more frequently-prescribed medication,[69] spent more money on advertising, and, as a result, generated more claims.

Xarelto lawsuit advertising began soon after the FDA's approval. Plaintiffs' law firms and lead generators concentrated additional advertising as trial dates were set and approached, anticipating that a plaintiff's verdict would make an inventory of cases more valuable to package, sell, and settle.

As plaintiffs lost each and every case because the risks of the medication were well understood by doctors, advertising for additional claims slowed. Still, given the number of people taking Xarelto and the understood bleeding risk, the ads generated over 30,000 lawsuits. This dynamic provided leverage for plaintiffs' law firms to pressure a global settlement, and J&J agreed to settle the claims for $775 million. Though they did not prevail in a single Xarelto case, plaintiffs' lawyers will pocket up to $93 million in fees and $23 million in costs from the settlement. Their clients will eventually receive a few thousand dollars each.

What is not captured by this business model is the adverse impact that hundreds of thousands of television commercials have on viewers relying on Xarelto who did not experience any issue with their medication. Commercials repeatedly told these patients that the anticoagulant prescribed by their doctors to prevent a stroke could kill them. Last year, nine FDA researchers searched the FDA's Adverse Event Reporting System (AERS) and identified 66 reports of patients who discontinued their anticoagulant after viewing a lawsuit ad, usually without consulting with their doctor.[70] Half of these patients (33) experienced a stroke, seven people died, and 24 people experienced other serious injuries. Most of the victims

were senior citizens.[71] The reports mostly involved patients discontinuing the use of Xarelto (55 of the 66 reports), though there were also reports stemming from lawsuit ads targeting other new anticoagulants, Pradaxa and Elloquis.[72] The study includes reports filed through November 15, 2017, covering the peak of Xarelto lawsuit advertising. These figures likely significantly understate the number of injuries and deaths, as few doctors, patients, or their families may think to report attorney advertisements to the FDA or even be aware that an ad sparked a patient's decision to stop taking his or her medication.

"These figures likely significantly understate the number of injuries and deaths, as few doctors, patients, or their families may think to report attorney advertisements to the FDA or even be aware that an ad sparked a patient's decision to stop taking his or her medication."

Case Study: Talcum Powder Litigation

Plaintiffs' lawyers and lead generating firms have spent an estimated $63 million on 175,000 television commercials telling viewers that baby powder and other talc-based cosmetics cause cancer. Spending on lawsuit ads spikes with plaintiffs' verdicts; declines with dismissals, mistrials, defense verdicts, and reversals of excessive awards; and levels off during periods of mixed results. Weaknesses in these claims may explain why talc lawsuit advertising is comparable to investing in a volatile stock. Plaintiffs' lawyers who invest in talc lawsuits bet that if they generate enough claims, and defendants experience adverse publicity and some significant losses, the defendants will settle regardless of whether a person's cancer had any link to their product. Thus far, the combination of targeting commonly-used talc products and a common illness has generated roughly 18,000 lawsuits.

About Talc and Talcum Powder Products

Talc is the world's softest mineral. It is mined primarily in China, India, Brazil, South Korea, the United States, France, Japan, and Finland.[73] In the United States, talc is found on the eastern side of the Appalachian Mountains and in rocks metamorphosed in convergent terranes of Washington, Idaho, Montana, California, Nevada, New Mexico, and Texas.[74] Once removed from the ground, talc is crushed, sorted, assigned a grade, milled, and tested. Talc is used in making plastics, ceramics, paint, paper, and roofing materials.[75] Talc is also used in cosmetics, because it has the ability to absorb oils and perspiration produced by human skin.[76]

J&J began selling its iconic Baby Powder in 1894. The product is made up of talc and a

small amount of fragrant oil that provides its well-known scent.[77] While initially marketed to new mothers to help relieve their babies' skin irritation and diaper rashes, adults soon began using it to keep skin cool and dry.[78] J&J also marketed another talc product, Shower to Shower, until its sale to Valeant Pharmaceuticals in 2012. Several other companies sell similar products containing talc, such as Colgate-Palmolive (Cashmere Bouquet) and Chattem, Inc. (Gold Bond Medicated Powder), or supply talc used in cosmetics, such as Imerys Talc America and Whittaker, Clark & Daniels.

Public Health and Safety Assessments

Recent litigation generally alleges that talc-based cosmetics cause ovarian cancer or, if contaminated with asbestos, ovarian cancer or mesothelioma.

While some have suggested that long-term use of talc may result in increased incidences of cancer, any connection between uncontaminated talc and cancer is unproven. The American Cancer Society (ACS) estimates that about 21,750 women will be diagnosed with ovarian cancer in 2020.[79] Women have a 1-in-78 likelihood of developing ovarian cancer in their lifetime, and the risk increases with age, family history, and first becoming pregnant late in life or not at all.[80] The Centers for Disease Control and Prevention includes ethnic background, genetic mutations, and estrogen use among risk factors, but not talc exposure.[81] In other words, ovarian cancer may have nothing to do with a person's talc use.

> *"In 2014, the FDA evaluated the scientific research and rejected a request to mandate that products containing talc warn that frequent application can cause women to develop ovarian cancer."*

The FDA has observed that "published scientific literature going back to the 1960s has suggested a possible association between the use of powders containing talc and the incidence of ovarian cancer," but that studies have not proven such a link.[82] In 2014, the FDA evaluated the scientific research and rejected a request to mandate that products containing talc warn that frequent application can cause women to develop ovarian cancer.[83] After careful review, the FDA found insufficient scientific evidence to warrant such a warning.[84] Likewise, the National Cancer Institute, a sub-agency of the U.S. Department of Health and Human Services, has observed that "the weight of evidence does not support" a link.[85]

The ACS described outcomes of the many scientific studies that have researched a link between talc and ovarian cancer as "mixed" and observed that studies finding an association are potentially biased.[86] The ACS has cautioned against fear over talc-

“Most recently, a federally-funded study consisting of data from more than 250,000 women who used talc—the largest study to date—found no statistically significant increased risk of developing ovarian cancer.”

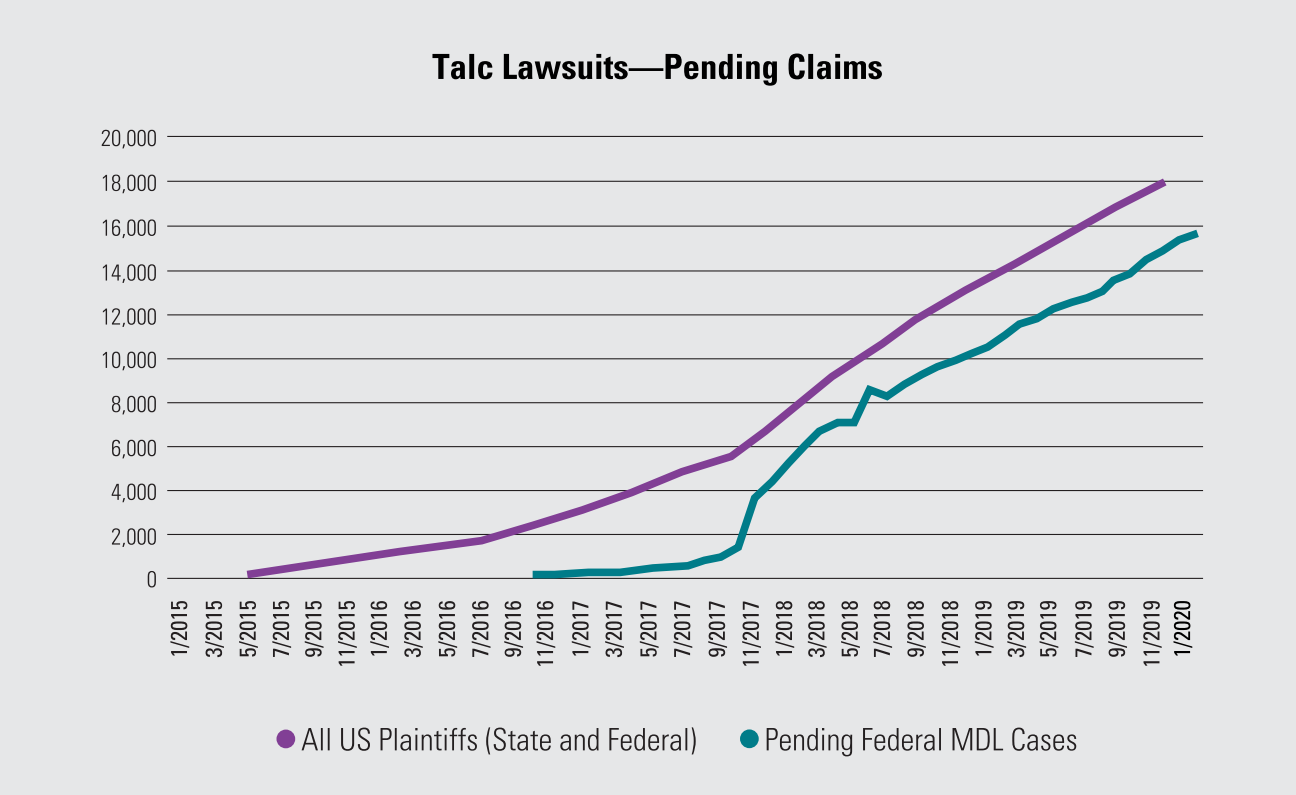
based products, noting that even “if there is an increased risk, the overall increase is likely to be very small.”[87]

Earlier however, in 2006, the International Agency for Research on Cancer (IARC) found that perineal (pelvic) use of non-asbestos-containing, talc-based body powder is “possibly” carcinogenic.[88] IARC, however, also views hotdogs, deli meats, smoked and cured fish, [89] and, until recently, coffee as “possibly” or “probably” carcinogenic. (Instead, IARC now says that all “very hot” drinks probably cause cancer).[90] Cancer experts have criticized IARC’s classification process as “placing too much weight on isolated findings that appear to suggest a risk, while ignoring more solid studies that do not support the existence of risk.”[91]

According to J&J, thousands of tests over the past 40 years repeatedly confirm that the company’s consumer talc products do not contain asbestos.[92] People may develop mesothelioma as a result of exposure to asbestos,[93] which can occur through multiple sources and job sites, or through asbestos carried home from work on a family member’s clothing.[94]

The FDA notes that questions about potential contamination of talc with asbestos have been raised, but not confirmed, for decades.[95] Since 2018, the FDA has routinely tested cosmetic products containing talc for asbestos contamination.[96] While the vast majority of tests detected no asbestos fibers, there have been a handful of exceptions, the most recent of which involved J&J’s Baby Powder.[97] Out of an abundance of caution, the company immediately recalled the single lot at issue in October 2019 while it investigated whether the result could stem from a false positive or counterfeit product.[98] Two third-party laboratories then conducted 15 tests on the same bottle tested by the FDA and an additional 48 tests on samples from the same lot.[99] None found asbestos, leading J&J to conclude that the FDA results reported in October 2019 were influenced by contamination during storage or analysis.[100]

Most recently, a federally-funded study consisting of data from more than 250,000 women who used talc—the largest study to date—found no statistically significant increased risk of developing ovarian cancer.[101]



An Overview of the Litigation

About 18,000 lawsuits allege that J&J's Baby Powder and former Shower to Shower products caused a person to develop cancer.[102] Other cosmetic manufacturers and talc suppliers face similar litigation.

The foundation for what would later become a surge of claims was set in October 2013 with a verdict in a South Dakota federal court finding that asbestos-free talcum powder in J&J's Baby Powder and Shower to Shower caused the plaintiff's ovarian cancer.[103] Though the jury awarded her no damages, plaintiffs' lawyers viewed the case as "groundbreaking."[104] The following month, a New Jersey jury awarded $1.6 million in the first case to succeed in alleging that talc was contaminated with asbestos. That plaintiff alleged that he developed mesothelioma as a result of talc that his father brought home on his clothes from work at a cosmetic manufacturer.[105] In early 2014, plaintiffs' lawyers filed consumer class action lawsuits against J&J in California and Illinois,[106] and personal injury claims began to mount in Atlantic County, New Jersey.

New Jersey established a centralized proceeding for talc lawsuits filed in state courts in November 2015.[107] About one year later, federal courts established an MDL for claims alleging talc caused ovarian cancer in the District of New Jersey.[108] At that point, J&J faced about 2,400 lawsuits, including 47 in federal court.[109] Today, about 75 percent of talc litigation is in the federal MDL.[110] The other claims are primarily in state courts in California, Missouri (St. Louis), and New Jersey.[111]

Early lawsuits typically alleged that talc itself is carcinogenic, causing ovarian

"The talc litigation relies on a small group of well-paid expert witnesses hired by plaintiffs' lawyers to establish a link between talcum powder and the plaintiffs' cancer."

cancer. By 2018, however, the litigation evolved to focus on claims asserting that talc is contaminated with asbestos, which the suits allege causes ovarian cancer or mesothelioma.[112] Observers attributed this change in strategy to the weak science attributing ovarian cancer to talc.[113] Focusing on asbestos—known to cause lung cancer and mesothelioma—provided plaintiffs' lawyers with a way to persuade judges and juries that cosmetic products can cause cancer.

The talc litigation relies on a small group of well-paid expert witnesses hired by plaintiffs' lawyers to establish a link between talcum powder and the plaintiffs' cancer.[114] For example, one of those witnesses, Dr. William Longo, reportedly has collected $31 million from plaintiffs' lawyers for his testimony in talc cases.[115] Dr. Longo claims to have detected traces of asbestos in old samples of Baby Powder. His testimony has repeatedly come under fire due to questionable testing methods and the origin of the samples used, among other issues.[116]

A New Jersey court found that two other experts who served as plaintiffs' principal witnesses on causation presented a "narrow and shallow" analysis that "slanted away from objective science and towards advocacy."[117] In those cases, Judge Nelson Johnson reviewed "approximately 100 treatises relating to talc, cancer, and miscellaneous related scientific issues" and found that the proposed experts failed to demonstrate "that the data or information used were soundly and reliably generated and are of a type reasonably relied upon by comparable experts."[118] Rather, the court observed that it had received a "*made-for-litigation* methodology."[119]

Litigation outcomes have been mixed. Most of the lawsuits to go to trial have been in state courts in St. Louis, California, and New Jersey. Early on, J&J was hit with several multimillion-dollar verdicts in ovarian cancer trials in St. Louis. The first—$72 million (*Fox*) in February 2016[120]—was viewed by plaintiffs' lawyers as a "game changer."[121] That verdict was soon followed in St. Louis by awards of $55 million (*Ristesund*),[122] $70 million (*Giannecchini*),[123] and $110 million (*Slemp*).[124] A Los Angeles ovarian cancer trial also resulted in a $417 million verdict in August 2017.[125]

Meanwhile, during this period, a New Jersey court tossed two cases due to the lack of reliable scientific evidence,[126] another St. Louis jury returned a defense verdict,[127] and a federal judge dismissed a consumer class action challenging the safety of Baby Powder.[128]

Since then, most cases that have gone to trial have alleged that asbestos in talc products is responsible for a person's development of mesothelioma. At the time of this publication, those cases have resulted in plaintiffs' verdicts in California,[129] New Jersey,[130] and New York.[131] They have also led to court dismissals in Pennsylvania and Wisconsin;[132] a series of mistrials in California,[133] Georgia,[134] and South Carolina;[135] and several defense verdicts in California,[136] Kentucky,[137] New Jersey,[138] and South Carolina.[139]

The largest verdict to date of $4.69 billion came from a St. Louis trial combining the claims of 22 women who alleged asbestos in Baby Powder caused their ovarian cancer. A defense attorney told the jury that the common thread between all the plaintiffs, most of whom had no connection to Missouri, was that they had found out about the alleged link between talcum powder and cancer by seeing attorney advertisements on television.[140] Nevertheless, in July 2018, the jury awarded each woman $25 million (even though each had different circumstances), each of their husbands $12.5 million, and added $4.14 billion in punitive damages.[141]

Already, several of the extraordinary verdicts have been thrown out by trial or appellate court judges as unsupported by the evidence, as excessive, or because they were brought in a plaintiff-friendly court in an area that lacked a sufficient connection to the litigation, including the $72 million and $110 million St. Louis verdicts, and the $417 million Los Angeles award.[142] Other plaintiffs' verdicts, including the $4.69 billion award, remain on appeal.

No case has reached trial in the federal MDL, which is considering the reliability of proposed expert testimony. Federal trials are expected to begin in late 2020. At the time of this publication, there are no publicly reported global settlement negotiations. J&J, the most frequent defendant, has indicated that it stands by the safety of its product and will defend itself in court. The company confidentially settled three mesothelioma cases in March 2019, but these appear to be isolated cases.[143]

Plaintiffs' lawyers have characterized the FDA test results and October 2019 recall as a "huge turning point" and "game changing moment in the litigation."[144] The impact of that recall, which appears to have stemmed from a false positive, is not yet clear. In the first trial presenting this information, a jury returned a defense verdict in an ovarian cancer case—in notoriously plaintiff-friendly

"Already, several of the extraordinary verdicts have been thrown out by trial or appellate court judges as unsupported by the evidence, as excessive, or because they were brought in a plaintiff-friendly court in an area that lacked a sufficient connection to the litigation ..."

St. Louis.[145] The company later settled mesothelioma cases in California and New York mid-trial, and was hit with a $9 million asbestos verdict in Florida.[146]

Talc lawsuits are big business. Many major plaintiffs' law firms are invested in this litigation. For example, in January 2020, HarrisMartin hosted a litigation conference at the Fontainebleau Miami Beach devoted to talc litigation.[147] The conference included attorneys from a dozen firms known for mass tort litigation as "faculty members." Presenters advised other lawyers interested in bringing talc lawsuits on topics including the status of the MDL, scientific and litigation developments, media reporting, and congressional activity, and provided an opportunity to coordinate their strategies.

Lawsuit Advertising Messaging

Lawsuit advertisements targeting talcum powder products focus on women diagnosed with ovarian cancer.[148] The relatively few lawsuit advertisements produced before the first large awards highlighted the 2007 IARC classification of talc as "possibly carcinogenic," or noted studies indicating an increased risk of ovarian cancer for talc users. Soon after, television commercials emphasized the February 2016 $72 million St. Louis verdict. Later ads highlighted subsequent plaintiffs' verdicts, such as the $4.69 billion verdict in July 2018. While some older ads indicated that talc fibers cause ovarian cancer, more recent ads assert that the presence of asbestos is to blame. Some ads tell viewers that defendants knew of the presence of asbestos in their products, a message that seems unnecessary for recruiting clients, but likely to prejudice potential jurors and pressure defendants to settle by harming their reputation.

Some ads may mislead viewers. For example, lengthy infomercials that began airing in 2020 feature an interview with a person introduced as Dr. Wendy Walsh, who explains to viewers the science underlying talc litigation, including studies that purportedly link talc to ovarian cancer.[149] Her name, including "Dr.," repeatedly flashes on the screen throughout the 30-minute ad. What viewers do not know is that Dr. Walsh is not an oncologist or an OB-GYN. She is not even a medical doctor. According to her YouTube page, she is "America's Relationship Expert," holding a B.A. in Journalism, a Master's degree in Psychology, and a Ph.D. in Clinical Psychology. Dr. Walsh is the author of several books, including "The Boyfriend Test" and "The 30-Day Love," and is the host of a radio show on relationships and a podcast called "Mating Matters."[150] Yet, viewers of the infomercial may believe she is an expert on cancer. (Dr. Walsh also is featured in similar infomercials discussing science allegedly linking Roundup to non-Hodgkin's lymphoma[151] and injuries associated with various prescription drugs, medical devices, and consumer products).[152]

Ferrer, Poirot & Wansbrough TV Commercial, "Talc Powder Ovarian Cancer," iSpot.tv, last aired Jun. 10, 2015.

Baron & Budd, P.C. TV Commercial, "Talcum Baby Powder Alert," iSpot.tv, last aired Apr. 22, 2016.

Onder Law Firm TV Commercial, "Johnson & Johnson," iSpot.tv, last aired Ju. 2, 2016.

Chaffin Luhana TV Commercial, "Talcum Powder," iSpot.tv, last aired Nov. 1, 2018.

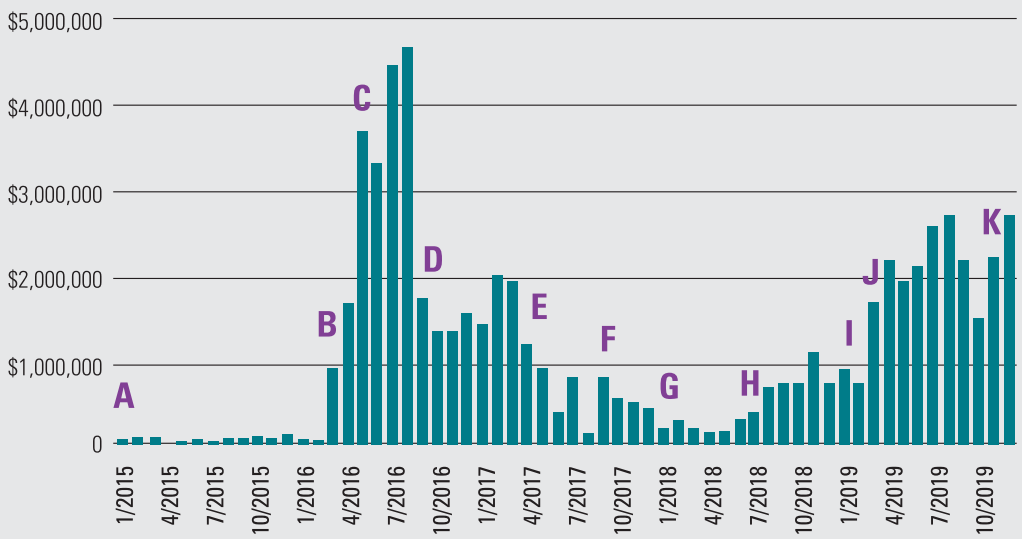
Goldwater Law Firm TV Commercial, "Talcum Powder: Over Four Billion," iSpot.tv, last aired Aug. 13, 2019.

Talcum Cancer Legal Helpline TV Commercial, "Regular Use," iSpot.tv, last aired Dec. 3, 2019.

Talcum Powder Alert TV Commercial, "Ovarian Cancer Diagnosis," iSpot.tv, currently airing.

Consumer Attorney Marketing Group, Legal Helpline: TALC Infomercial

Estimated Monthly Spending on Talcum Powder Lawsuit Advertising



Spending on Lawsuit Advertisements

According to data compiled by Kantar CMAG, plaintiffs' law firms and others have spent an estimated $63 million on television advertising to entice individuals with cancer who used talc-based consumer products, such as Baby Powder, to file a lawsuit, mostly during the past four years. This includes over 175,000 airings of these ads across the United States.

An analysis of the television advertising spot count and spending data reveals:

BENCHMARK A

Cable television ads begin in January 2015. This occurs after law firms tested the water with limited advertising after the first plaintiffs' verdicts in late 2013, which resulted in no damages or a modest award,[153] and after talc claims began to mount in Atlantic County, New Jersey in 2014. Advertising remains at low levels

through February 2016, averaging just $30,000 per month during this period. Early ads highlight IARC's classification of talc as "possibly carcinogenic" or state that talc users face an increased risk of ovarian cancer.

BENCHMARK B

Following the first major plaintiffs' verdict—a $72 million award—and the reported filing of 1,200 talc claims, advertising jumps. In March 2016, law firms and lead generators spend $865,250 on 1,412 ad spots—a rise from just $16,810 on 96 ad spots the prior month. Spending doubles in April 2016 to $1.6 million on 2,026 ad spots.

BENCHMARK C

After the second major verdict, $55 million in St. Louis, advertising skyrockets. The number of ads triples from the previous month to 6,080 at a cost of $3.6 million in May 2016. Over the next four months, plaintiffs' lawyers and lead generators spend a remarkable $15.8 million on over 33,000 ads—the largest four-month advertising run in the talc litigation. Ad spending peaks at $4.6 million in August 2016. At this point, J&J unsuccessfully requests that a court move talc trials out of the St. Louis Circuit Court, because a disproportionate amount of the television commercials aired in St. Louis, inundating potential jurors with the message "Talcum Powder linked to OVARIAN CANCER" and flashing multimillion-dollar verdicts.[154]

BENCHMARK D

Spending on advertising begins to dive in September 2016, possibly as a result of a New Jersey court's dismissal of a pair of talc cases as based on unreliable, made-for-litigation expert testimony. This ruling may send a message that large verdicts are a St. Louis phenomenon. The third St. Louis verdict—a $70 million award in late October 2016, does not change this trend. The level of advertising remains between $1.3 million and $1.9 million for seven months.

"Over the next four months, plaintiffs' lawyers and lead generators spend a remarkable $15.8 million on over 33,000 ads—the largest four-month advertising run in the talc litigation."

BENCHMARK E

Advertising takes another plunge, when it falls from $1.9 million in March to $350,000 in June 2017. While there is an uptick in spending in July, ad spending drops to about $100,000 in August 2017. This substantial decline may reflect the first St. Louis defense verdict in March (though there was also a $110 million St. Louis award in May). It may also respond to a U.S. Supreme Court ruling in June that found that state courts cannot hear claims that lack a connection to the state unless a corporate defendant is headquartered or incorporated there.[155] As a result of the ruling, a St. Louis trial court declares a mistrial in a talc case,[156] prior St. Louis verdicts are in jeopardy, and many pending nonresident claims appear likely to be dismissed.

BENCHMARK F

Spending on lawsuit advertising bounces back to about $750,000 in September 2017, likely as a result of a $417 million verdict in the first California trial.

BENCHMARK G

Another decline in lawsuit advertising follows as plaintiffs suffer a series of defeats, including courts excluding plaintiffs' experts in Philadelphia,[157] reversing the initial $72 million St. Louis verdict for jurisdictional reasons,[158] throwing out the $417 million California verdict as unsupported by the evidence,[159] and a Los Angeles defense verdict in the first case alleging that talc caused a person's mesothelioma.[160] While two California plaintiffs' verdicts and a New Jersey verdict finding talc products caused mesothelioma follow,[161] these results are tempered by mistrials in similar cases in California and South Carolina.[162] Lawsuit advertising averages under $200,000 per month during the first half of 2018.

BENCHMARK H

Advertising surges after a $4.69 billion St. Louis verdict in July 2018, likely to publicize the award. Spending on lawsuit ads doubles in the month after the award, eventually growing to $1 million in November 2018. This rise occurs despite a New Jersey defense verdict and two more California mistrials.

BENCHMARK I

Lawsuit advertising dips to $660,000 in December 2018, which may reflect a California defense verdict and South Carolina mistrial the prior month. Spending then rises 30 percent in January 2019, as a trial court maintains the $4.69 million judgment and the first talc settlement is reported in a mesothelioma claim in New York. Spending subsides in February with the first dismissal of a case blaming talc for mesothelioma in Philadelphia, a Missouri Supreme Court ruling requiring a case to be moved out of the City of St. Louis, and a talc supplier declaring bankruptcy because of the litigation.

BENCHMARK J

Spending on lawsuit advertising trends upward beginning in March 2019, generally running between $1.6 million and $2.6 million per month. Advertising hits a peak in July 2019 with 11,592 ad spots and a similar number of ads the following month. This surge may have been sparked by a reported settlement of three lawsuits in California, New York, and Oklahoma, which may have led plaintiffs' lawyers to

"After a $4.69 billion St. Louis verdict in July 2018, advertising surges, likely to publicize the award. Spending on lawsuit ads doubles in the month after the award, eventually growing to $1 million in November 2018."

> *On the other hand, the science indicating that talc use causes ovarian cancer is recognized as weak, uncertain, and biased by reputable organizations and some judges and juries.*

anticipate an increased likelihood of a global settlement. A $325 million mesothelioma claim in New York in May 2019 followed by another $37.3 million New York verdict and $40.3 million and $12 million California verdicts in similar cases may have contributed to the rise in advertising. A one-sided congressional hearing on the safety of talc, featuring plaintiff-affiliated witnesses, may have also been a factor.[163] This spending, however, may have been tempered by several defense verdicts, mistrials, and appellate rulings affirming trial courts that dismissed talc claims in California, Georgia, Kentucky, Missouri, and Wisconsin between April and August 2019.

BENCHMARK K

In October 2019, J&J voluntarily recalls a single lot of its Baby Powder after FDA monitoring detects a trace of asbestos. Although third-party laboratory tests indicate that the initial test was a false positive, lawsuit advertising rises from $1.4 million for 5,182 spots to $2.6 million for 7,466 spots between October and December 2019—an 85 percent spending increase.

Analysis

Talc lawsuits are a risky but potentially lucrative proposition for mass tort lawyers. On the one hand, the common use of talc-based products such as Baby Powder combined with the 22,000 women who are unfortunately diagnosed with ovarian cancer each year provides lawyers with a large pool of potential plaintiffs. It is for this reason that lawsuits ads have generated about 18,000 claims. On the other hand, the science indicating that talc use causes ovarian cancer is recognized as weak, uncertain, and biased by reputable organizations and some judges and juries. It is for these reasons that the lawsuits, and the advertisements for them, have shifted the focus from blaming talc itself for cancer to asserting that talc is contaminated with asbestos. Still, these newer claims face challenges given the years of talc testing that have found no trace of asbestos, the questionable expert testimony relied upon in the lawsuits, and the unlikeliness that a rare exposure to a trace amount of asbestos in talc, even if it occurs, would cause a person to develop mesothelioma or ovarian cancer.

> *"The weaknesses in these claims may explain why talc lawsuit advertising is comparable to investing in a volatile stock."*

The weaknesses in these claims may explain why talc lawsuit advertising is comparable to investing in a volatile stock. Spending on talc lawsuit ads rises with plaintiffs' verdicts; declines with dismissals, mistrials, defense verdicts, and reversals of excessive awards; and levels off during periods of mixed results. The largest ad spending spikes followed the initial multimillion-dollar St. Louis verdicts, which showed the potential for big wins and provided a headline to gain viewers' attention.

While courts have thrown out many of the blockbuster awards and the $4.69 billion verdict seems highly vulnerable on appeal, reports of a handful of individual settlements and a trickle of plaintiffs' verdicts have fueled continued lawsuit advertising. Ultimately, plaintiffs' lawyers that invest in talc lawsuits bet that if they generate enough claims, and defendants experience bad publicity and some significant losses, the companies will be pressured into settling the claims regardless of their merit.

Case Study: Roundup Litigation

Plaintiffs' law firms and lead generators have spent an estimated $103 million to air over 450,000 television commercials telling viewers that exposure to glyphosate, the primary ingredient in the herbicide Roundup, can cause non-Hodgkin's lymphoma and other cancers. The ads began after an international agency classified glyphosate as "probably carcinogenic to humans," contrary to findings by the U.S. Environmental Protection Agency and many other regulatory bodies. Data suggests one driver of the volume of lawsuit advertising is the proximity of a trial or large verdict. Spikes in spending in the months preceding or during a trial raise questions as to whether these ads serve purposes in addition to recruiting clients to file lawsuits. In this instance, rumor of a global settlement also appears to have led to heavy lawsuit advertising.

About Glyphosate

Since 1974, the U.S. Environmental Protection Agency (EPA) has approved the use of glyphosate to control invasive and noxious weeds in both agricultural and non-agricultural settings. Glyphosate is the active ingredient in Roundup, the most widely used herbicide in the United States. Roundup was developed by Monsanto, which Bayer acquired in 2018. Glyphosate is used on more than 100 food crops, including corn, soybean, cotton, canola, and sugar beet, as well as fruits, vegetables, cereals, nuts, herbs, and spices. Glyphosate is also commonly used to manage parks, forests, and residential and commercial areas.

Public Health and Safety Assessments

The EPA has repeatedly assessed the safety of glyphosate since the agency first registered the herbicide 45 years ago. After comprehensively evaluating the scientific evidence, the EPA continues to find that glyphosate poses no risk to public health

and that glyphosate is not a carcinogen. As recently as April 2019, the EPA shared the results of a safety evaluation that reaffirmed its findings based on the weight of the scientific evidence.[164]

In March 2015, however, IARC classified glyphosate as "probably carcinogenic to humans."[165] Because of the IARC classification, California regulators added glyphosate to a list of over 1,000 chemicals that the state maintains as "known to cause cancer" in 2017.[166] The following year, a federal judge, after considering the scientific evidence, prohibited California from requiring companies to place a cancer warning on products with traces of glyphosate, finding that doing so would violate the First Amendment by forcing them to make "false, misleading and highly controversial statements" about their products.[167] The EPA has likewise instructed companies not to place California's mandated cancer warning labels on products containing glyphosate.[168]

The EPA's 2019 assessment indicates that the agency's evaluation of glyphosate's effect on human health was more comprehensive, participatory, and transparent than the IARC review, and that the EPA's conclusion that glyphosate does not cause cancer is consistent with the findings of many other regulatory authorities and international organizations.[169] Investigative reporting later revealed that IARC failed to consider significant scientific data,[170] that a key section of the IARC monograph was edited to delete multiple scientists' conclusions that their studies had found no link between glyphosate and cancer in laboratory animals,[171] and that an advisor to IARC received $160,000 from law firms suing Monsanto.[172]

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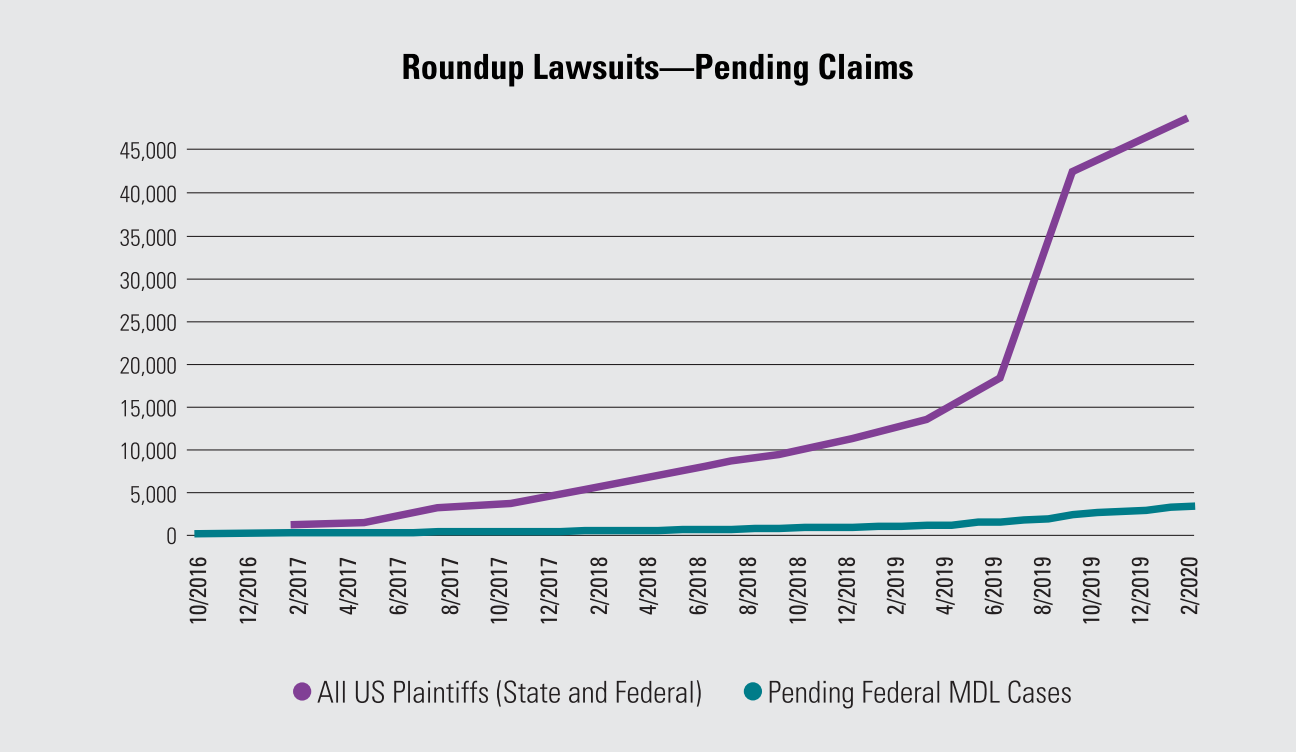

An Overview of the Litigation

Within six months of the IARC monograph, plaintiffs' attorneys began filing lawsuits against Monsanto alleging that their clients' cancer stemmed from exposure to Roundup. The first lawsuits, filed in September 2015, blamed Roundup for a farm worker's bone cancer and a horticultural assistant's leukemia diagnosis.[173] The following month, *Reuters* reported, "personal injury law firms around the United States [were] lining up plaintiffs" to bring mass tort litigation against Monsanto.[174]

Since then, most lawsuits have claimed that exposure to Roundup is responsible for a plaintiff's development of non-Hodgkin's lymphoma (NHL), a cancer that starts in white blood cells called lymphocytes, which are part of the body's immune system. The American Cancer Society indicates that the cause of NHL, like other lymphomas, is unknown, but that risk factors for developing NHL include age (higher as one gets older), gender (higher for men), race (Caucasians are more likely to develop), family history, exposure to radiation, a weakened immune system, and contraction of certain autoimmune diseases and infections.[175] The Mayo Clinic includes certain medications, viruses, and bacteria among the risk factors.[176] Both organizations recognize that some studies have tied NHL to chemicals including herbicides, but that more research is needed to determine if there is a link.

Nevertheless, personal injury attorneys have filed lawsuits on behalf of over 48,000 people with NHL and other cancers over the past four years, alleging that Roundup is to blame.[177] As the number of lawsuits grew and with more claims anticipated, the federal judiciary established an MDL

> *"The federal judge overseeing the Roundup MDL ... has characterized the science linking glyphosate to NHL as 'shaky' and 'pretty sparse' ..."*

proceeding in the U.S. District Court for the Northern District of California for actions alleging that Roundup can cause NHL and that Monsanto failed to warn consumers and regulators about this risk.[178] The federal docket began with 21 cases in October 2016 and has since grown to about 3,000 lawsuits from across the country.[179] However, about 75 percent of the litigation is in St. Louis, Missouri courts, where Bayer's crop science business is headquartered[180] and where there is a history of "fast trials, favorable rulings, and big awards."[181] California also hosts significant litigation, and the state opened its own special docket for Roundup lawsuits in November 2017.[182] Additional litigation is scattered across other state courts.

The federal judge overseeing the Roundup MDL, U.S. District Judge Vince Chhabria, has characterized the science linking glyphosate to NHL as "shaky" and "pretty sparse," [183] but has ruled that he will allow some of the plaintiffs' experts to testify, allowing potential weaknesses in their theories to be exposed at trial.[184] There have been three massive plaintiffs' verdicts, each of which trial court judges substantially reduced. These verdicts include a $289 million award to a schoolyard groundskeeper in San Francisco state court in August 2018 (reduced to $78 million),[185] an $80.2 million award to a California homeowner in the first federal trial in March 2019 (reduced to $25.3 million),[186] and a $2 billion award to a California couple in an Alameda County state court in May 2019 (reduced to $86.7 million).[187]

Soon after the $2 billion verdict, Judge Chhabria appointed Ken Feinberg as mediator in an effort to reach a settlement.[188] In July 2019, Bayer CEO Werner Baumann indicated that the company would consider a reasonable settlement, given the mounting lawsuits, verdicts, and impact on the company's stock.[189] An August 2019 rumor of an $8 billion offer that would settle all pending cases was quashed by Feinberg as "pure fiction."[190]

Meanwhile, 2019 closed with the arrest of one of the plaintiffs' attorneys involved in the initial $289 million Roundup verdict.[191] Timothy Litzenburg was charged by federal prosecutors with attempted extortion for allegedly threatening to bring an unidentified company that may have supplied chemical compounds to Monsanto into the Roundup litigation unless the company paid him $200 million in "consulting" fees.[192]

Lawsuit Advertising Messaging

The typical television commercial indicates that studies suggest that Roundup's main ingredient, glyphosate, may cause cancer, announces that thousands of lawsuits have already been filed claiming Roundup causes NHL, and urges viewers to "call now" for a free consultation.[193] Some ads not only link Roundup to NHL, but also assert the product may cause an assortment of other cancers. The ads sometimes specifically target farm workers, landscapers, and homeowners.[194] Some ads emphasize IARC's classification of glyphosate, flashing the agency's official logo.[195] A few ads highlight court developments, such as a July 2018 ruling "determining that all federal lawsuits could move forward."[196] (The court found that the plaintiffs' expert witnesses' opinions that glyphosate can cause NHL "while shaky, are admissible," leading the court to deny a request to exclude their testimony and dismiss the cases).[197]

Most recent ads highlight massive verdicts, suggesting that individuals diagnosed with cancer may be entitled to a portion of that money or a similar sum.[198] Ads flash the full amount of each verdict without indicating that trial court judges substantially reduced each award. Ads have even dangled the potential to receive money from an $8 billion settlement,[199] which, as noted, was a rumor that Ken Feinberg quickly debunked.

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While some ads indicate the name of the law firm sponsoring them, others run under names such as the "Injury Help Desk," "Legal Helpline," or "RoundupCase.com." The name of the law firm or lead-generating company that sponsored the ad may be tucked into the usually unreadable fine print at the conclusion of the commercial.[200]

Baum Hedlund Aristei & Goldman, PC, "Monsanto Roundup Weed Killer Linked to Cancer," YouTube, posted Apr. 12, 2016.

Monsanto Roundup Lawsuit Commercial, "Roundup Cancer Lawyer," YouTube, posted May 11, 2017.

Fears Nachawati Law Firm TV Commercial, "Roundup Lawsuit," iSpot.tv, last aired Oct. 25, 2019.

Marc Whitehead & Associates, LLP TV Commercial, "Monsanto Roundup," iSpot.tv, last aired Nov. 9, 2019.

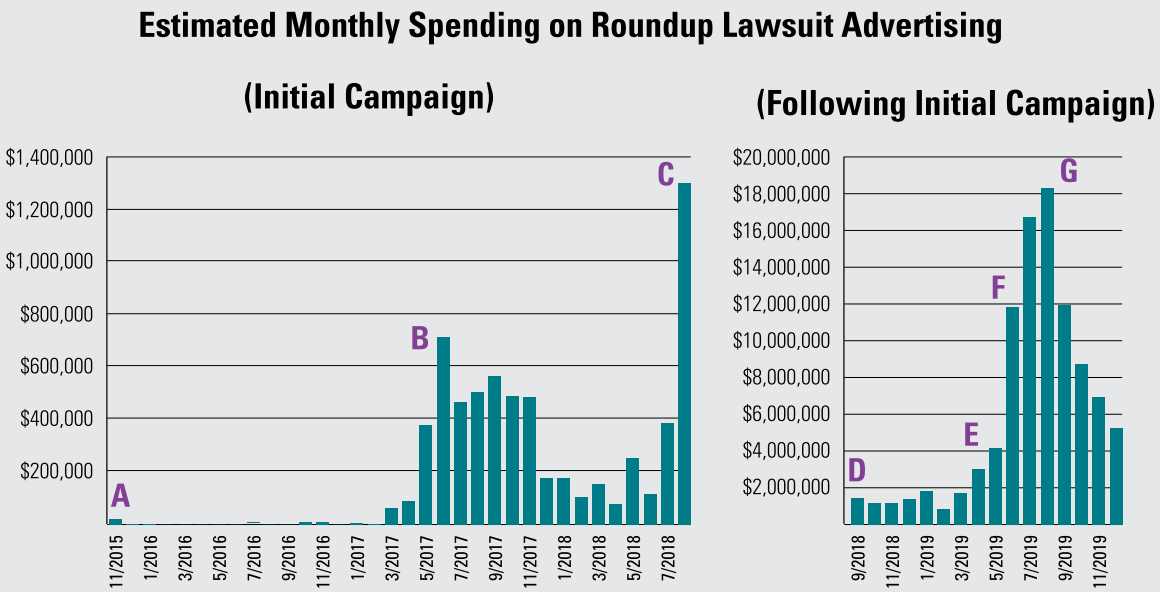
Injury Help Desk TV Commercial, "Roundup Compensation," iSpot.tv, last aired Dec. 4, 2019.

Negligence Network TV Commercial, "Roundup," iSpot.tv, last aired Jan. 5, 2020.

Chaffin Luhana TV Commercial, 'Roundup Weed Killer', iSpot.tv, last aired Jan. 17, 2020.

Sokolove Law TV Commercial, "Monsanto Roundup & Cancer," iSpot.tv, last aired Feb. 14, 2020.

Roundup Legal Helpline TV Commercial, "Choose the Right Legal Team," iSpot.tv, last aired Mar. 5, 2020.



Spending on Lawsuit Advertisements

According to data compiled by Kantar CMAG, plaintiffs' law firms and others have spent an estimated $103 million on television advertising to entice individuals with cancer who used Roundup to file a lawsuit against Monsanto. This includes over 450,000 airings of these ads across the United States. Three quarters of this lawsuit ad spending ($80 million) occurred between June and December 2019.

In the closing months of 2019, Roundup was the top target of mass tort lawsuit advertising with five times more ads aired than talcum powder products, the next most popular target.[201] These ads have inundated television viewers and infected the jury pool. For example, when attorneys questioned potential jurors for a January 2020 trial in St. Louis, nearly every person

raised his or her hand when asked if they had seen a lawsuit ad seeking individuals with cancer who had been exposed to Roundup.[202] Some of the prospective jurors reportedly "conflate[d] the ads with news reports, saying initially that they'd heard about a Roundup-cancer link on TV, and then clarifying that they'd seen an ad."[203] One member, who was ultimately not chosen to serve on the jury, said the ads aired so frequently they were "bordering on harassment."[204]

As the *Wall Street Journal* has observed, "behind the surge in [Roundup] lawsuits is a little-known, sophisticated legal ecosystem that includes marketing firms that find potential clients, financiers who bankroll law firms, doctors who review medical records, scientists who analyze medical literature and the lawyers who bring the cases to court."[205] Law firms pay as much as $6,000 for each potential lead for a Roundup plaintiff to marketers that run the ads. Potential clients are routed to call centers, some of which are outside the United States, for screening.[206] While some law firms will sign up only those who regularly have used Roundup for many years, others will sign up almost anyone who used the product and developed NHL.[207]

An analysis of the television advertising spot count and spending data reveals:

BENCHMARK A

The first Roundup lawsuit ads begin in November 2015, about eight months after IARC classified glyphosate as "probably carcinogenic to humans." That month, 355 spots air at a cost of about $13,500. Soon after, two of the three lawsuits that resulted in multimillion-dollar verdicts *(Johnson* and *Hardeman)* are filed.

BENCHMARK B

Plaintiffs' lawyers and lead generators begin to spend hundreds of thousands of dollars each month on Roundup lawsuit ads in May 2017. This level of spending begins soon after a trial court rejects a challenge to a California agency's requirement, based on IARC's classification, that businesses selling products with glyphosate must label them as known to cause cancer. It also occurs after an EPA Scientific Advisory Panel divides on whether evidence shows

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glyphosate is carcinogenic. Spending about $500,000 each month becomes the new normal for the six-month period running from June to November 2017.

BENCHMARK C

The next substantial jump in advertising occurs in August 2018 when spending surpasses $1 million. While plaintiffs' lawyers place 281 ad spots in July 2018, they subject television viewers to 12 times as many ads the following month (3,503). This advertising binge begins within one month of a ruling by the judge overseeing the federal Roundup docket that, despite relying on shaky science, the cases will go to trial. The spike also occurs as trial is underway in the first Roundup case in state court *(Johnson)*, which resulted in a $289 million verdict in San Francisco on August 10, 2018.

BENCHMARK D

After the $289 million verdict, though spending does not rise significantly, ad spots double to 7,113 in September 2018 at a cost of approximately $1.4 million. Ad spending remains between $1.1 million and $1.8 million in each of the next four months.

BENCHMARK E

After briefly slowing, ad buys return to their previous level in March 2019—$1.7 million for nearly 13,000 ads. That month, the second Roundup trial *(Hardeman)* is underway and ends in an $80 million verdict on March 27, 2019. The third Roundup trial *(Pilliod)* begins the next day. As that trial is underway, spending soars to $3 million, funding over 16,000 Roundup lawsuit ads in April 2019.

> *"Spending peaks in August 2019 as over 70,000 ads air at an estimated cost of $18.3 million when unfounded rumors swirl about an $8 billion global settlement."*

BENCHMARK F

After the $2 billion verdict on May 13, 2019, spending on lawsuit ads rises exponentially.

BENCHMARK G

Spending peaks in August 2019 as over 70,000 ads air at an estimated cost of $18.3 million when unfounded rumors swirl about an $8 billion global settlement. Spending then subsides to the still-extraordinary $5.2 million level at year-end.

Analysis

The data suggests that a significant driver of spending on Roundup lawsuit advertisements is the proximity of a trial or large verdict. Although television ads recruiting plaintiffs for Roundup lawsuits began in late 2015, about one quarter of the ads (107,597 spots at a cost of $26.6 million) ran during the month of a trial or in the month immediately preceding or following a trial. In fact, 40 percent of all ads (178,872 ads at a cost of $46.2 million) ran during the month of a trial or within the two months before or two months after a trial.

> *Large verdicts trigger spikes in lawsuit ad spending. Plaintiffs' lawyers present these verdicts as breaking news, suggesting that viewers should call now as they may receive a similar award.*

Lawsuit advertising during this period may serve several purposes. The most controversial reason to run ads just prior to or during a trial, as it is improper, is to influence the jury pool. Local residents are inundated with commercials telling them that an international agency, IARC, or "some studies" have found that glyphosate in Roundup may cause cancer. While defense lawyers may strike individuals during jury selection who have been influenced by ads and courts may instruct jurors to avoid watching television during the trial, some impact from this nonstop messaging is presumably unavoidable.

Ironically, during the *Pilliod* trial, plaintiffs' lawyers filed a motion to stop Monsanto from running any advertisement that mentions safety, testing, or studies related to Roundup. The request for an injunction was spurred in part by a single advertisement in the *Wall Street Journal* on March 25, 2019, which plaintiffs' lawyers viewed as posing a risk to the jury selection process in Alameda County, California. In opposition to the motion, Monsanto's attorneys pointed out the plaintiffs' lawyers had "bombarded" the jury pool with 2,187 television and radio ads in the local media market alone disparaging Roundup in the four months before trial.[208] One Roundup lawsuit ad aired an average of eight times a day.[209] Just seven days before the *Pilliod* trial, plaintiffs' lawyers placed an ad in the *San Francisco Chronicle* alleging a "doubling or tripling" of the risk of NHL from Roundup.[210] The court denied the request for a one-sided gag order.[211]

Large verdicts trigger spikes in lawsuit ad spending. Plaintiffs' lawyers present these verdicts as breaking news, suggesting that viewers should call now as they may receive a similar award. For example, in the three months following the $2 billion *Pilliod* verdict, plaintiffs' lawyers invested nearly $50 million into 160,000 television commercials. The ads do not tell viewers that trial courts often slash these excessive verdicts, or that the awards may be further reduced or reversed on appeal.

The increase in spending following a large verdict may also indicate that plaintiffs' lawyers are reinvesting a portion of their contingency fee earnings (or the expectation of receiving a fee following an appeal or settlement) to generate future cases. In addition, it may be a sign that plaintiffs' lawyers are attempting to generate as many cases as possible as the likelihood of a global settlement grows. For instance, the rumor of an $8 billion settlement in early August 2019 coincided with the largest monthly spending on lawsuit advertising. This may suggest a rush by lead generators and law firms to find clients who are potentially eligible to receive a payout.

Case Study: Zofran Litigation

Plaintiffs' lawyers and lead generators spent $13 million to air approximately 30,000 television commercials telling viewers that using the anti-nausea medication Zofran during pregnancy causes birth defects. Nearly all of this spending occurred in a six-month period in 2015 when Zofran was a top target of lawsuit ads. A scientific study, which the FDA later found to be flawed, sparked the litigation. Investors in Zofran litigation took a gamble that their ads would generate a significant number of highly sympathetic plaintiffs and that the FDA would grant a pending petition to require changes to Zofran's label to caution against use during pregnancy. Neither of those bets paid off. Spending quickly plummeted as the ads failed to produce viable claims and the FDA rejected the unnecessary warnings sought in the litigation. The relatively few cases generated by the ads and the likelihood that the cases will eventually be dismissed appear to have led plaintiffs' lawyers to spend their advertising dollars elsewhere.

About Zofran

The FDA approved ondansetron, developed by GlaxoSmithKline (GSK) and marketed as Zofran, in 1991 for treating nausea and vomiting after chemotherapy and surgery.[212] Doctors also legally prescribe Zofran "off-label" for nausea and vomiting during pregnancy (NVP), though the FDA has not approved it for this purpose.[213] The most severe form of NVP is hyperemesis gravidarum, which, while rare, can be life-threatening. There were no FDA-approved medications for NVP available until recently, leaving doctors and their patients to either rely on off-label prescriptions or use herbal treatments, supplements, or over-the-counter

> *"After receiving GSK's analysis of the then-available safety data, the FDA did not require any labeling changes."*

medications.[214] GSK's patent for Zofran expired in 2006, allowing the sale of generic versions of ondansetron. GSK transferred the patent for Zofran along with other oncology drugs to Novartis in 2015.[215]

Public Health and Safety Assessments

Some have questioned whether Zofran, when taken by pregnant women, increases the risks of having a baby with birth defects, particularly cleft lip, cleft palate, and congenital heart defects. The FDA, however, has repeatedly found that scientific evidence does not support these concerns.[216]

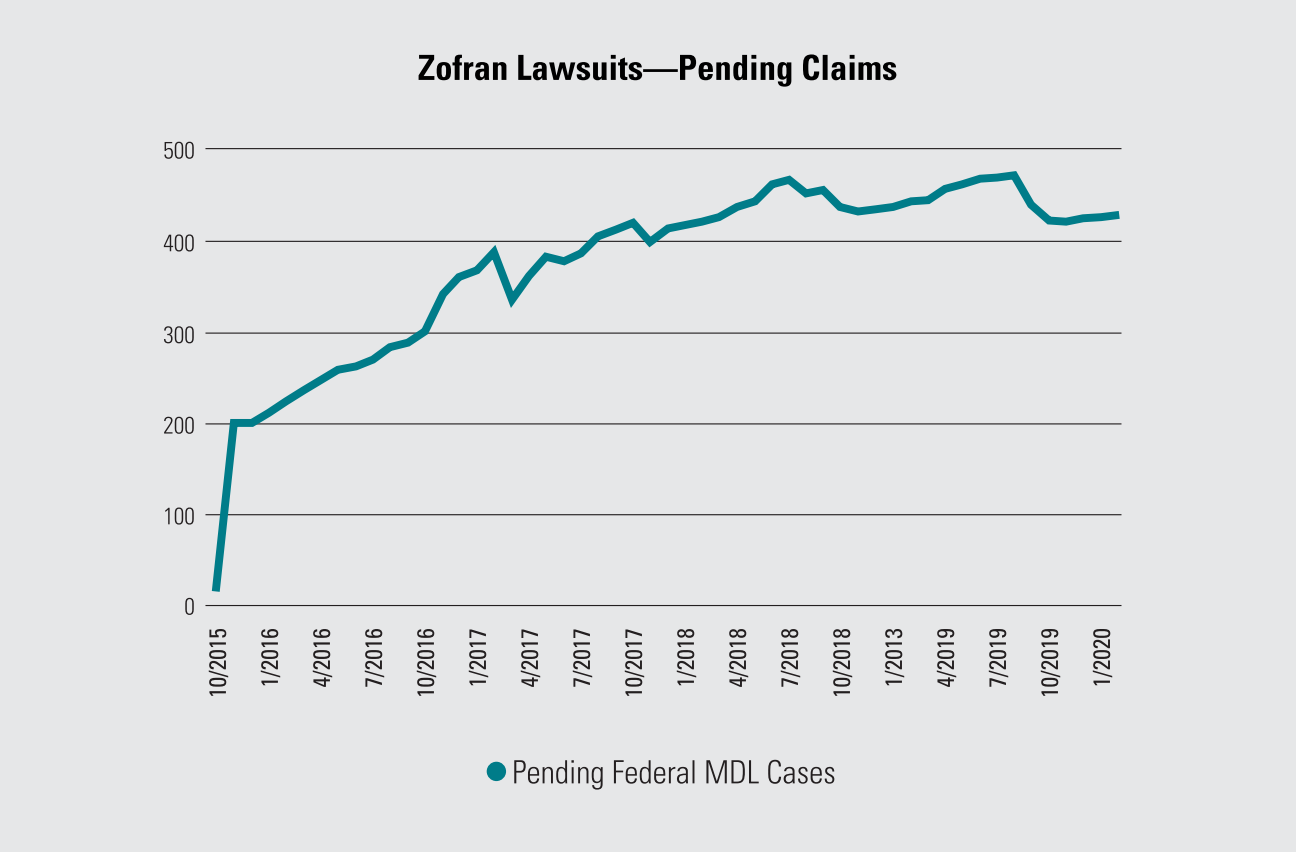
In 2010, after the FDA became aware that doctors were increasingly prescribing Zofran for NVP, the agency requested that GSK provide information concerning the safety of the medication when used during pregnancy. After receiving GSK's analysis of the then-available safety data, the FDA did not require any labeling changes.[217]

Soon after Novartis acquired Zofran in 2015, the company submitted a proposed label change that included a warning that use in pregnancy could cause harm to the fetus and is not recommended. The FDA rejected Novartis's proposed change.[218]

In October 2015, the FDA thoroughly reevaluated the available scientific research. The agency's review came in response to a Citizen Petition[219] filed by Dr. James R. Reichmann, requesting that the FDA reclassify Zofran to reflect a higher risk when taken during pregnancy and to notify OB/GYNs that the drug may lead to adverse maternal and fetal events.[220] The FDA denied the petition, finding the requests "not necessary," potentially misleading, and unsupported by available data. The FDA detailed its analysis of scientific literature supporting its conclusions in a 20-page response.[221]

Communication between the FDA and Novartis regarding whether Zofran's label should change to recommend against ondansetron use during pregnancy continued into 2016, with the FDA repeatedly declining to authorize a label change. For example, the FDA found "no evidence ... that raises concerns for adverse fetal outcomes with Zofran."[222] Rather, the FDA observed that "[i]nclusion of such statement would not only be unhelpful to prescribers, but it could be misleading in implying that FDA has some concerns about the role of Zofran in a variety of fetal malformations."[223] Instead, the FDA mandated that Zofran's label include language indicating that the available data and studies do not show that usage of Zofran during pregnancy causes adverse fetal outcomes.[224]

In November 2019, GSK filed its own Citizen Petition with the FDA, asking the agency whether information that plaintiffs' lawyers allege was withheld from the agency would lead the FDA to approve a change in the drug's labeling.[225] That petition is pending.



An Overview of the Litigation

There are currently over 400 pending Zofran claims,[226] virtually all of which are in a federal MDL in the U.S. District Court for Massachusetts.[227]

The first reported lawsuits alleging that usage of Zofran during pregnancy led to babies born with birth defects were filed in early 2015.[228] In addition to citing studies that purportedly show an association between Zofran use for NVP and birth defects, the lawsuits emphasize that, in 2012, GSK agreed to pay a substantial fine to settle allegations that the company had improperly promoted Zofran and several other medications for "off-label" uses that were not approved by the FDA.[229]

By July 2015, plaintiffs' lawyers had filed at least a dozen lawsuits blaming Zofran for a wide range of birth defects.[230] GSK requested that the Judicial Panel on Multidistrict Litigation coordinate cases in federal courts for pre-trial purposes, and the judiciary established an MDL in October 2015.[231] By the following month, federal courts had transferred 200 cases to the MDL. The number of Zofran claims has gradually risen over the past four years. In total, plaintiffs' lawyers have filed about 700 lawsuits.[232] About 300 of those claims have been dismissed, most of them voluntarily. The court has also dismissed some claims brought against GSK by plaintiffs who did not take Zofran but used a generic version of the drug.[233]

The federal litigation has focused on whether the plaintiffs may proceed with their claims despite the FDA's repeated rejection of the need for warnings regarding

the risk of using Zofran during pregnancy. The U.S. Supreme Court has ruled that personal injury lawsuits alleging that an FDA-approved medication should carry different or stronger warnings are preempted by federal law if there is "clear evidence" that the FDA would not have approved the label change sought in the litigation.[234] In January 2016, Judge F. Dennis Saylor, who is overseeing the federal litigation, denied a motion to dismiss on this basis, finding that at that early stage of the litigation, "plaintiffs are entitled to an opportunity to develop the record as to how the FDA would have responded to a proposal [to change the label] had GSK submitted one."[235]

In February 2019, after the plaintiffs had an opportunity to conduct discovery to support their claims, Judge Saylor found "little doubt that the FDA *would have* rejected plaintiffs' proposed warning: it in fact *did* reject it, at least in substance."[236] Nevertheless, the court found that whether GSK fully disclosed material data about Zofran to the FDA and whether allegedly withheld data would have changed the agency's decision on the drug warning's label was an issue of disputed fact for juries to decide.[237]

Three months after Judge Saylor issued this opinion, the U.S. Supreme Court ruled in an unrelated case that judges, not juries, must evaluate whether clear evidence indicates that the FDA would have rejected changes to drug labels sought by plaintiffs.[238] In light of this decision, Judge Saylor vacated his earlier ruling on preemption and invited GSK to again seek summary judgment[239]: the motion was promptly submitted in July and remains pending.[240] The court, however, denied a motion to dismiss 48 cases blaming Zofran for an assortment of birth defects aside from cardiac defects and isolated cleft palate, finding plaintiffs offered sufficient expert testimony on general causation to allow the cases to move forward.[241] The first bellwether trial had been scheduled to begin on May 4, 2020, but has been delayed indefinitely due to COVID-19.[242]

Lawsuit Advertising Messaging

Television commercials seeking to recruit plaintiffs for Zofran lawsuits targeted women who have a child born with heart defects, cleft palate, or cleft lip. Some ads asserted that Zofran may be responsible for a wider range of birth defects or health problems, "even death." The warnings contained in the ads, some of which were

"The U.S. Supreme Court has ruled that personal injury lawsuits alleging that an FDA-approved medication should carry different or stronger warnings are preempted by federal law if there is 'clear evidence' that the FDA would not have approved the label change sought in the litigation."

presented as a "medical alert," conflicted with the FDA's repeated evaluation of scientific evidence. One ad, for example, presented Zofran as a "bad drug," even as it remains approved by the FDA and prescribed by physicians.

In addition, some Zofran lawsuit ads flashed the FDA logo, telling viewers, for example, that the "FDA Never Approved Zofran for use in Pregnant Women." Other ads misleadingly emphasized a $3 billion settlement between the federal government and GSK in 2012 (some ads refer to it as a $2 billion settlement, excluding a separate portion of the settlement completely unrelated to Zofran).[243] This settlement resolved claims that the company had marketed Zofran for off-label uses, but it primarily involved practices involving other medications, was unconnected to personal injury claims, and did not place any restriction on the ability of doctors to prescribe Zofran to treat NVP.

Daniel N. Gallucci TV Commercial, "My Zofran Lawsuit," iSpot.tv, last aired Mar. 1, 2015.

Parilman & Associates TV Commercial, "Zofran Warning," iSpot.tv, last aired Mar. 22, 2015.

Saiontz & Kirk, P.A. TV Commercial, "Zofran Alert," iSpot.tv, last aired Apr. 22, 2015.

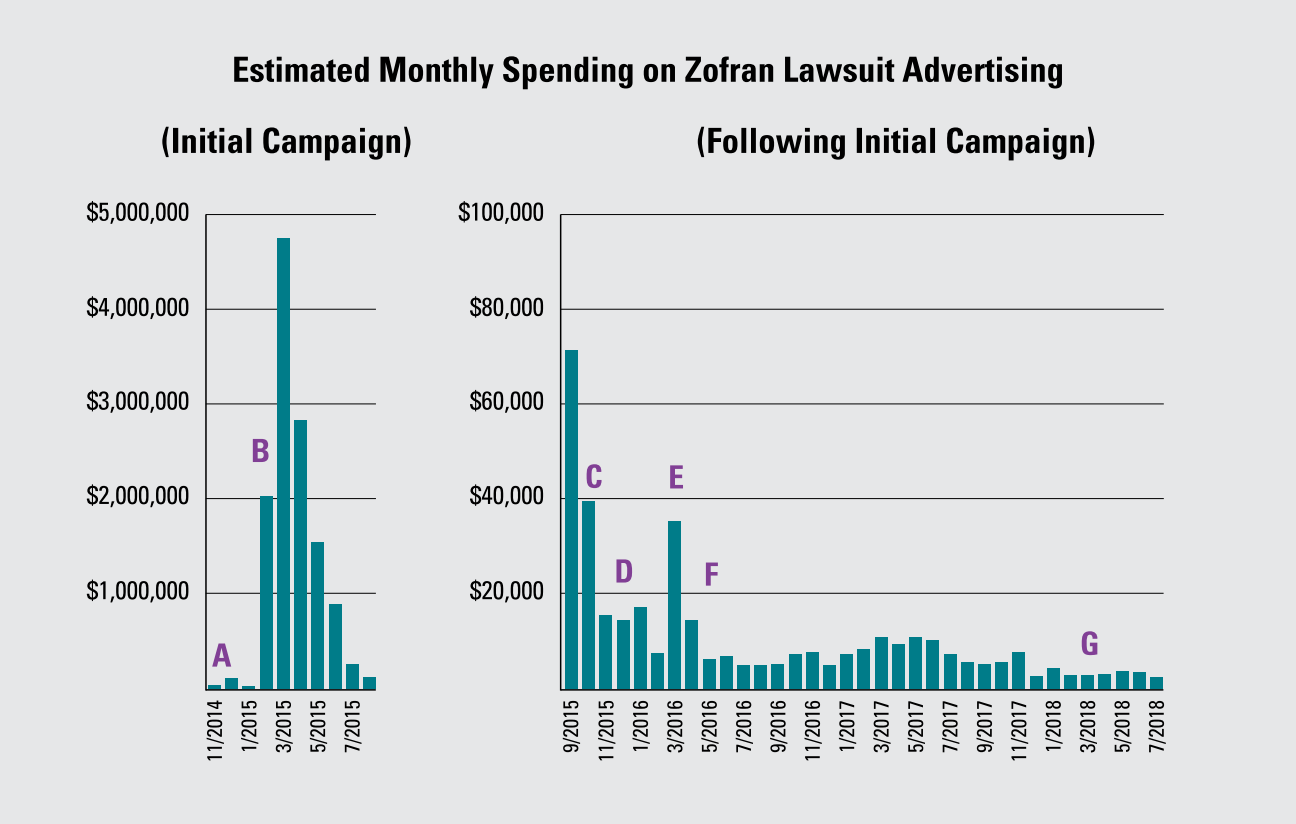
Willis Law Firm TV Commercial, 'Zofran Birth Defect Warning', iSpot.tv, last aired Apr. 25, 2015.

Pulaski & Middleman TV Commercial, "Zofran Birth Defect Warning," iSpot.tv, last aired May 22, 2015.

Sokolove Law TV Commercial, "Zofran Birth Defects," iSpot.tv, last aired May 28, 2015.

Crumley Roberts TV Commercial, 'Zofran Birth Defects', iSpot.tv, last aired July 10, 2015.

Parilman & Associates TV Commercial, "Zofran Legal Helpline," iSpot.tv, last aired Apr. 8, 2016.



Spending on Lawsuit Advertisements

According to data compiled by Kantar CMAG, plaintiffs' law firms and others spent an estimated $13 million on about 30,000 television ads to entice women who took Zofran while pregnant to file a lawsuit. While the litigation has continued for five years, about 95 percent of the spending on lawsuit ads occurred in just six months at the litigation's outset in 2015. Zofran was among the top five drugs and medical devices targeted for lawsuits that year.[244] By the end of 2015, however, Zofran advertising had fallen to minuscule levels and, by mid-2018, the ads ended.

An analysis of the television advertising spot count and spending data reveals:

BENCHMARK A

Zofran lawsuit advertisements begin in November 2014 with a modest $39,000

> *"While the litigation has continued for five years, about 95 percent of the spending on lawsuit ads occurred in just six months at the litigation's outset in 2015."*

investment for 60 ads and surpassed $100,000 the next month. A study of Swedish birth records by Dr. Bengt R. Danielsson, published on October 31, 2014,[245] appears to have sparked this campaign. Plaintiffs' lawyers heavily relied on this study to generate and support litigation[246] and retained Dr. Danielsson as an expert witness in the Zofran MDL.[247] The FDA[248] and other researchers later identify limitations and flaws in that study.[249]

BENCHMARK B

Ad spending explodes to $2 million for over 1,300 ad spots in February 2015, when the first reported lawsuits are filed.[250] Lawsuit advertising quickly peaks in March 2015 when about 8,000 commercials air in a single month at a cost of $4.7 million.[251] During the six-month period between February and July 2015, plaintiffs' lawyers spend $12 million on Zofran lawsuit ads, 95 percent of the total spent on ads over five years of litigation.

BENCHMARK C

The heavy spending in 2015 appears to have generated relatively few viable claims, as just 200 cases are transferred to the MDL when it is formed in October 2015. By that time, advertising has plummeted to 416 ads targeting the medication.

BENCHMARK D

On October 27, 2015, the FDA denies a Citizen Petition requesting that the agency require Zofran's label to warn of potential risks associated with its use by pregnant women. The following month, spending drops to just $13,300 for 191 ad spots.

BENCHMARK E

A slight advertising bump in March 2016—the last time spending would exceed $10,000—may reflect increased optimism for a settlement after the federal court handling Zofran litigation denies a motion to dismiss.[252]

BENCHMARK F

Spending on lawsuit ads remains at a low level in late 2015 and 2016, as the FDA repeatedly rejects proposals by Zofran's new owner, Novartis, to warn of reports of congenital malformations and indicate "[t]he safety of ondansetron for use in human pregnancy has not been established." The FDA finds these statements could mislead the public.[253] Meanwhile, a May 2016 study finds no connection between the medication and birth defects.[254] These developments may have further led plaintiffs' lawyers and lead generators to look elsewhere for lawsuits. From May 2016 on, spending did not exceed $10,000 for fewer than 50 ads per month.

BENCHMARK G

Advertising slows to a trickle in 2018, never exceeding $2,000 in a month and ending mid-year, as it appears increasingly likely that the federal court overseeing Zofran claims will dismiss them as preempted by federal law.

Analysis

The plaintiffs' bar's brief but heavy investment in Zofran was triggered by a Swedish scientific study, the results of which were later called into question by the FDA and other research. The earlier $3 billion civil settlement of federal allegations that GSK promoted Zofran and

> *"The plaintiffs' bar's brief but heavy investment in Zofran was triggered by a Swedish scientific study, the results of which were later called into question by the FDA and other research. … Plaintiffs' lawyers and lead generators likely determined that further investment in advertising would be unlikely to lead to the number of claims needed to pressure a global settlement."*

other drugs for off-label uses provided additional ammunition for lawsuit ads. A pending Citizen Petition urging the FDA to classify Zofran as having greater risks if taken during pregnancy and to mandate stronger warnings presented an opportunity to gamble that the FDA would require the change, bolstering the lawsuits.

The plaintiffs' bar may have overestimated the number of lawsuits that their initial $12 million advertising surge would generate. The ads ultimately sparked about 700 claims, which works out to an investment of about $17,000 in advertising per claim filed. Considering that nearly half of these claims were dismissed either voluntarily by plaintiffs (possibly due to weak science or other flaws) or by a court, the advertising cost per claim pending is about $30,000. While the 430 or so Zofran claims pending in the MDL involve highly sympathetic plaintiffs, these numbers pale in comparison to the number of claims generated from advertising in other mass tort litigation. Plaintiffs' lawyers and lead generators likely determined that further investment in advertising would be unlikely to lead to the number of claims needed to pressure a global settlement.

Plaintiffs' lawyers may have believed that even if advertising generated a relatively small number of lawsuits, Zofran cases would lead to extraordinarily high damage awards and settlements because they involve children. After five years of litigation, however, a case has yet to reach trial.

Plaintiffs' lawyers and lead generators also lost their gamble that the FDA would grant a pending Citizen Petition and require Zofran's label to caution against use during pregnancy. They likely did not anticipate the FDA's thoroughly-reasoned denial of the petition in October 2015—just two weeks after the federal judiciary established an MDL for Zofran litigation. Plaintiffs' lawyers now faced a strong argument that the FDA's consistent and repeated action on the very issue in the litigation preempted their claims, as well as mounting science finding that the use of Zofran during pregnancy presented little or no increased risk of birth defects. Given the few claims generated by the lawsuit ads and the increasing likelihood that courts will ultimately dismiss the claims, plaintiffs' lawyers appear to have decided to spend their advertising dollars elsewhere.

Findings and Conclusion

An examination of lawsuit advertising data and litigation events reveals common trends in spending behavior and messaging across the five mass tort litigations studied. Most notably, spending on lawsuit advertising rises with events that suggest an increased likelihood that plaintiffs' lawyers and lead generators will receive a generous return on their investment. Blockbuster verdicts appear to have the most significant impact on ad spending. To get viewers' attention, television commercials often flash extraordinary multimillion or billion-dollar awards and settlements and employ a plethora of misleading practices. The pervasiveness of fearmongering lawsuit ads poses a risk to public health and the ability to receive a fair trial.

The Lawsuit Advertising Lifecycle

TRIGGERING EVENT

Mass tort advertising typically is sparked by a particular event, such as an investigation, study, or other action involving a product. These types of events send a message to plaintiffs' lawyers and lead generators that the litigation may be a worthy investment. For example:

- A government investigation of a product's safety, even if that investigation later deems concerns unfounded, can trigger lawsuit advertising. This occurred after the FDA indicated in late 2011 that it would investigate reports of "serious bleeding events" in patients taking Pradaxa.
- Publication of a study that suggests an association between a product and an illness or other harm can spark lawsuit advertising, even if that association is weak or the study is flawed. The Zofran litigation began immediately after the publication of a Swedish study that suggested a link between the use of the

nausea-reducing drug during pregnancy and cardiovascular defects. The FDA later recognized limitations in that study that called its findings into question.

- Actions taken by organizations such as IARC can spark lawsuit advertising. As discussed earlier, IARC has a history of classifying even the most commonly used products and substances as "possibly" or "probably" carcinogenic. IARC's classification played a prominent role in early talc and Roundup lawsuit ads.

OPTIMISM-GENERATING EVENT

Advertising increases following events that might suggest that the litigation is likely to reach trial and has a chance of success. This may include a court denying a motion to dismiss, scheduling bellwether cases for trial, an approaching trial, a modest plaintiff's verdict, a regulatory action that raises concern, or reports of individual settlements. For instance:

- When the MDL court scheduled four bellwether Xarelto cases for trial in September 2015, advertising seeking Xarelto plaintiffs rose from averaging about $2.7 million in the six prior months to $4.8 million in the six months that followed. Xarelto lawsuit advertising jumped again in early 2017 as the first trial date approached.

- Roundup lawsuit advertising swelled in March 2017 when a trial court rejected a challenge to a California agency's addition of glyphosate to the state's list of chemicals known to cause cancer and, soon after, an EPA panel divided on the carcinogenic potential of glyphosate.

> *"A government investigation of a product's safety, even if that investigation later deems concerns unfounded, can trigger lawsuit advertising."*

Advertising rose from just three ad spots the preceding month to 539 ad spots in March and continued to escalate in the months that followed.

SURGE-GENERATING EVENT

Lawsuit advertising spikes after blockbuster awards, which appear to have the greatest impact on spending levels. Extraordinary awards may lead plaintiffs' lawyers and lead generators to believe that a business is likely to settle the litigation to avoid further risk of liability and damage to its reputation. For that reason, advertising may surge to generate as many claims as possible, overwhelm defendant companies, and claim a larger share of the settlement pie. Other events suggesting that a global settlement may occur can also influence spending. For example:

- The first talc lawsuits were filed in 2013 and advertising began in 2015, averaging about $30,000 per month. Only after the first large verdict—$72 million in February 2016—did monthly ad spending climb toward $1 million. The second

> *Lawsuit advertising spikes after blockbuster awards, which appear to have the greatest impact on spending levels.*

large verdict, $55 million, led monthly ad spending to spike to $3.6 million and peak, soon after, at $4.6 million.

- In the Roundup litigation, plaintiffs' lawyers went from airing 281 advertising spots in the month before the first large verdict ($289 million on August 10, 2018) to 3,503 ad spots the month of the verdict, to 7,113 ad spots the following month at a cost of $1.4 million. The $2 billion award to a California couple on May 13, 2019 had an even more pronounced effect. Ad spending rose from $3 million the prior month to $4.2 million the month of the verdict, then to $11.9 million, $16.7 million, and $18.3 million in the three months that followed. The $18.3 million peak also coincided with rumors of an $8 billion global settlement.
- Advertising for Xarelto lawsuits took off after a May 2014 announcement of a $650 million settlement in the similar Pradaxa litigation. Before the Pradaxa settlement, spending on Xarelto advertising was less than $3,000 per month. Ad spending increased each month in the five months that followed, peaking at $6.5 million in October 2014.

ADVERTISING-DEPRESSING EVENT

Plaintiffs' lawyers and lead generators typically reduce lawsuit advertising when events occur that lead them to question the soundness of their investment in the litigation. These benchmarks include a court dismissing a claim or rejecting the plaintiffs' expert testimony as unreliable, a jury returning a defense verdict, or an agency action finding that science does not support the claims made in the litigation. For instance:

- Spending on Xarelto lawsuit advertising dropped after three consecutive defense verdicts in 2017 and additional plaintiff defeats in 2018.
- Spending on talc lawsuit advertising fell when the early blockbuster verdicts were followed by dismissals, defense verdicts, exclusions of plaintiffs' experts offering unreliable testimony, and courts' throwing out some of the initial plaintiff wins.
- Zofran lawsuit advertising began to drop off when initial heavy ad spending did not generate many claims. Ad spending then plummeted after the FDA found proposed changes to the medication's label that would have cautioned against use during pregnancy were unsupported by scientific evidence and misleading to the public.

Advertising Content Trends

SHIFTING ALLEGATIONS OF HARM

Early lawsuit advertisements tend to cast a broad net for potential plaintiffs by asserting that the product may cause a wide range of illnesses. As courts reject these claims as unsupported by science, or more thorough studies cast doubt on preliminary findings, the product risks communicated in lawsuit ads narrow or change.

For example, as seen in the highlighted television commercials in the Roundup litigation section of this report, early ads contended that the herbicide caused leukemia and bone cancer, among other conditions. Only later did the ads focus on non-Hodgkin's lymphoma. Similarly, the range of birth defects purportedly associated with Zofran in lawsuit ads appears to have narrowed over the course of the litigation.

The messaging of lawsuits ads may also shift to reflect the plaintiffs' mass tort litigation strategy. For example, initial talc lawsuit advertisements asserted that exposure to talc causes ovarian cancer. As plaintiffs' lawyers struggled in court to provide reliable scientific evidence supporting this claim, the lawsuits ads (and litigation) shifted to emphasize the alleged contamination of talc-based products with asbestos.

AWARDS PROMINENTLY FEATURED

Lawsuit ads prominently feature blockbuster awards, settlement amounts, and civil fines. It appears that plaintiffs' lawyers and lead generators find that flashing multi-million dollar amounts on television is effective in motivating viewers to respond. The ads may give the false impression that viewers may receive a similar result or that they are entitled to receive a portion of that amount.

Advertisements quickly incorporate extraordinary awards into their content. In both the talc and Roundup litigation, for example, advertising content adjusted to include recent awards. The ads do not reflect that trial and appellate court judges often throw out or substantially reduce outsized awards as unsupported by the evidence, excessive, or contrary to law. In some instances, ads continue to publicize a massive award long after a court slashes it.

Even when there is no large verdict to highlight, advertisements find another dollar figure to get viewers' attention. For example, Xarelto ads emphasized the $650 million settlement of the early Pradaxa claims. Zofran ads flash "$2 billion settlement" (or $3 billion), which, as discussed earlier, involved a settlement with the U.S. Department of Justice that

"As courts reject these claims as unsupported by science, or more thorough studies cast doubt on preliminary findings, the product risks communicated in lawsuit ads narrow or change."

> *"The ads may give the false impression that viewers may receive a similar result or that they are entitled to receive a portion of that amount. [...] Some ads give the misleading impression that viewers may already be entitled to compensation from a verdict or settlement."*

did not involve personal injuries, did not address the safety of Zofran, and primarily addressed marketing and pricing issues related to other drugs. The unfounded rumor of an $8 billion global settlement of Roundup litigation also made its way into lawsuit ads.

Some ads give the misleading impression that viewers may already be entitled to compensation from a verdict or settlement. For example, after displaying the $650 million Pradaxa settlement, one ad told viewers, "You could use this money to help with the tough and complicated time your family has gone through."[255] A Roundup lawsuit ad also told viewers that they may be entitled to substantial compensation "WITHOUT GOING TO COURT," both before and after highlighting a $289 million verdict.[256] Mass tort litigation, however, is not like the consumer class actions with which the public has become all too familiar. One cannot simply fill out a claim form and receive a check. An individual lawsuit must be filed and settled.

MISLEADING ADVERTISING PRACTICES

Lawsuit ads often incorporate practices that mislead viewers, aside from their display of large awards. As detailed in the U.S. Chamber Institute for Legal Reform's 2017 study, *Bad for Your Health: Lawsuit Advertising Implications and Solutions*, these practices include introducing the advertisement as a "medical alert," presenting the ad in a news-type format, flashing the official logo of a government agency, overstating the risks of a drug, implying that the product has been recalled, and hiding information identifying the ad sponsor in unreadable fine print.[257] Many of these practices are visible in the screenshots of television commercials displayed in each section of this report.

An emerging practice is to introduce a "doctor" who explains the science purportedly supporting the litigation, though that person's expertise is in a wholly unrelated field. As discussed in the talcum powder litigation section, a series of long-form infomercials and shorter ads feature Dr. Wendy Walsh, who is presented as "Doctor Wendy" and who explains the science supposedly linking the product to cancer. Not disclosed to viewers is that Dr. Walsh is a dating and relationship expert, not an oncologist or OB/GYN or even a medical doctor. Dr. Walsh is featured in similar infomercials for Roundup, Truvada, earplug, hernia mesh, IVC filter, asbestos, and child sexual abuse litigation.[258]

Public Policy Implications

PUBLIC HEALTH CONCERNS

Misleading lawsuit advertising raises public health concerns.[259] The exaggerated risks and dire warnings conveyed in these ads can undermine a physician's decision to prescribe medication after carefully considering his or her patient's condition. The ads can also give the misimpression that regulators or health officials have found that a product is dangerous and should not be used, when that is not the case. As detailed in the Xarelto litigation section of this paper, reports filed with the FDA document scores of instances in which patients stopped taking their prescribed medication after viewing a frightening lawsuit ad without speaking with their doctor. As a result, they suffered strokes and other serious injuries, with seven deaths reported.[260]

In 2019, the American Medical Association found that the misleading practices identified in this report have become "even more pervasive" in recent years and called upon state legislatures to protect patient health.[261] Thus far, three states—Tennessee, Texas, and West Virginia—have enacted legislation to do just that.[262] The Federal Trade Commission also has warned law firms and lead generators to avoid these types of misleading practices in mass tort advertising.[263]

Lawsuit ads that attempt to generate a new mass tort soon after the FDA approves a new medication or medical device raise unique concerns. Some uncertainty regarding a new product is inevitable. Regulators, medical professionals, and researchers closely monitor new treatments and investigate reports of adverse events that may relate to the product. It may become the norm for plaintiffs' lawyers and lead generators to attempt to capitalize off this process by airing television commercials targeting new products for lawsuits immediately upon initiation of an investigation or publication of preliminary research. If this occurs, the litigation is likely to discourage the development and use of life-saving or life-improving treatments and raise the cost of drugs and medical devices.

PREJUDICING THE JURY POOL

The pervasiveness of television commercials telling viewers that consumer products, pharmaceuticals, and medical devices are dangerous and cause harm may poison the jury pool. As documented in this report, lawsuit advertising often rises as cases approach and go to trial. The messaging of some lawsuit ads seems to focus more on broadly conveying to the public that a product is harmful, or that a business engaged in misconduct, than on recruiting potential clients. In some instances, lawsuit advertising may be

> *"The ads can also give the misimpression that regulators or health officials have found that a product is dangerous and should not be used, when that is not the case."*

> *"The messaging of some lawsuit ads seems to focus more on broadly conveying to the public that a product is harmful, or that a business engaged in misconduct, than on recruiting potential clients."*

concentrated in the very community in which a trial is scheduled or underway. For example, it may be no coincidence that St. Louis, the 23rd largest media market in the country, was the top area for lawsuit ads targeting talc-based products in 2016—the same period that St. Louis courts returned a series of multi-million dollar talc verdicts.[264]

Conclusion

Plaintiffs' lawyers and lead generators can manufacture mass tort litigation through misleading, fearmongering ads. Legislators, regulators, and courts each have a role to play in ensuring that these ads do not mislead the public, harm public health, or jeopardize the right to a fair trial.

Little is needed to spark mass tort litigation. An agency initiating an investigation into concerns regarding a product's safety or a preliminary study suggesting an association between a product and an illness, for example, may light the fuse. A large population of people with a common illness also provides an opportunity to point the finger at a company or product as the cause. Already, websites are springing up asking, "Were you infected or did a loved one die from coronavirus infection that could have been prevented? Find out if you have a case."[265] Events such as these can quickly prompt plaintiffs' lawyers and lead generators to spend tens of thousands or hundreds of thousands of dollars per month on television commercials to solicit claims. When there is a sign that the litigation may be successful, such as an initial large plaintiffs' verdict, spending on advertising can surge to millions of dollars per month.

As the case studies in this paper show, spending on lawsuit advertising rises and falls primarily based on the perceived likelihood that a defendant will enter a global settlement. As cases mount, defendants are pressured to settle due to the cost of never ending litigation, the risk of liability (particularly in areas viewed as plaintiff-friendly), and damage to their reputations. When judges and juries repeatedly find that these claims are not supported by sound science or the law, plaintiffs' lawyers cut their losses, running fewer ads. The driving force is profit—whether the amount spent on advertising and litigation is likely to yield a lucrative return on the investment.

Attorney advertising is commercial speech that is protected by the First Amendment[266] and it can serve a valuable purpose in linking people who are injured as a result of wrongful conduct with a lawyer. Legislators and regulators can and should step in, however, when lawsuit advertising misleads the public, jeopardizes public health, or undermines the right to a fair trial.[267]

Courts also need to protect the right to a fair trial. As spending on lawsuit advertising rises, lawyers and judges will need to even more closely monitor, through the *voir dire* process, whether the ability of prospective jurors to render impartial justice has been impaired after repeatedly viewing inflammatory ads. Where lawsuit ads declaring that a product is harmful or even that a business engaged in misconduct have besieged an area in which a case is scheduled for trial, courts may need to move the trial elsewhere.

> *"Legislators and regulators can and should step in … when lawsuit advertising misleads the public, jeopardizes public health, or undermines the right to a fair trial."*

Endnotes

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EXHIBIT F

NewsRoom

10/23/14 Legal Monitor Worldwide (Jordan) (Pg. Unavail. Online)
2014 WLNR 29641645

Legal Monitor Worldwide (Jordan)

October 23, 201420141023190605

Attorneys Handling Baby Powder Lawsuits Help Families of Women Suffering from Ovarian Cancer

Lawyers handling baby powder lawsuit claims related to ovarian cancer for the Onder Law Firm are reaching out to families through the firm's Talcum Powder Ovarian Cancer Center website. Persons whose mother, wife, or other loved one was diagnosed with ovarian cancer and has a history of baby powder use may be eligible to real compensation through filing a baby powder lawsuit. The firm provides no cost, no obligation case review and timely baby powder cancer news and updates. Johnson & Johnson is facing litigation on two levels regarding the purported link between talcum powder and ovarian cancer. First, the pharmaceutical giant is embroiled in at least two baby powder class action lawsuits, one in Illinois and the other in California. Secondly, the makers of talcum powder hygiene products have already lost at least one baby powder lawsuit in which a jury confirmed a connection between perineal talcum powder use and the development of ovarian cancer.* The baby powder case in Illinois, Barbara Mihalich v. Johnson & Johnson (Case No. 3:14-cv-00600-MJR-SCW in the U.S. District Court for the Southern District of Illinois) is currently underway. This particular case seeks to establish a class among Illinois women who bought talcum powder products within the past five years and "expected talc to be safe to use", according to court documents. The labels on Johnson & Johnson talcum powder products, including Johnson's Baby Powder and Shower to Shower, do not contain a warning for the risk of ovarian cancer, according to court documents. The baby powder lawsuit in California is much the same. In Mona Estrada v. Johnson & Johnson (Case No. 2:14-cv-01051-TLN-KJN, in the U.S District Court for the Eastern District of California), plaintiff Mona Estrada alleges negligence, false advertising, concealing information, and misrepresenting a product based on the lack of warning regarding the risk of developing ovarian cancer from using talc baby powder. The California baby powder lawsuit calls for a mandatory warning label on J&J's talc products. The first baby powder lawsuit was won against Johnson & Johnson during 2014 when a South Dakota federal jury confirmed that Ms. Deane Berg, the plaintiff, developed ovarian cancer as a result of her routine and prolonged use of talc baby powder products for perineal dusting. This outcome gave hope to plaintiffs throughout the country wishing to take legal action against Johnson & Johnson and the talc mining companies Luzenac America and Rio Tinto Materials. The lawsuit, filed on April 30, 2014 in the United States District Court in the Southern Division of South Dakota, is known as Deane Berg v. Johnson & Johnson, Case 4:09-cv-04179-KES. Johnson & Johnson is facing litigation from many corners this year. The company, known for its family-oriented products such as Tylenol and baby soap, has issued a substantial number of product recalls in the past five years, ranging from over-the-counter drugs like Children's Tylenol to major medical devices such as De Puy hip replacement parts, according to a timeline published by Reuters in February of 2012.** In a long tradition of serving American families, The Onder Law Firm's baby powder attorneys are offering a free case evaluation for persons who mother, wife, or other family member has suffered from ovarian cancer and has a history of using talcum powder. Families who meet this description may contact a lawyer through the firm's website for a no-obligation consultation on whether they have grounds for a baby powder lawsuit. The firm's lawyers believe women who meet this description may be entitled to real compensation for the harm and damages they sustained while the makers and manufacturers of baby powder benefited from their business.

---- Index References ----

News Subject: (Health & Wellness (1HE60); Major Corporations (1MA93))

Industry: (Baby Care (1BA96); Baby Products (1BA60); Consumer Products & Services (1CO62); Cosmetics & Fragrances (1CO83); Healthcare (1HE06); Healthcare Practice Specialties (1HE49); Medical Equipment & Supplies (1HE68); Personal Care & Beauty Aids (1PE87); Women's Health (1WO30))

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Other Indexing: (Barbara Mihalich; Deane Berg; Mona Estrada)

Word Count: 624

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EXHIBIT G

Friday, June 11, 2021

Attorneys Provide New Case Summaries for Talcum Powder Cancer Lawsuits

Share Article

The Onder Law Firm's talcum powder lawyer group has updated its website, TalcumPowderOvarianCancerCenter.com, where the firm offers talcum powder and ovarian cancer lawsuit news and information.

ST. LOUIS MO (PRWEB) DECEMBER 16, 2014

The Onder Law Firm

Attorneys handling talcum powder cancer claims for the Onder Law Firm have updated their website to include case summaries of current and past talcum powder lawsuits. Among these summaries is information on a talcum powder lawsuit filed and recently concluded in Missouri which represented an attempt to establish a class among Missouri women who have purchased Johnson's Baby Powder for personal use, according to official court documents accessed by the Onder Law Firm's talcum powder attorneys.*

"Cases such as this one distract the public from the real problem. While this case was filed on behalf of healthy individuals seeking remuneration for the cost of talcum powder, other talcum powder cancer lawsuit claims** have been successful at achieving justice for persons suffering from ovarian cancer. As part of our mission to support American families who have been wrongfully harmed by dangerous consumer products, the talcum powder lawyers at the Onder Law Firm are committed to pursuing justice on behalf of women and the families of women who believe they have been harmed by talcum powder. No matter how complex the case, our firm has committed its significant resources to providing the best talcum powder lawsuit services available," said Jim Onder regarding the Missouri class action suit.

In this talcum powder lawsuit, plaintiffs cite scientific studies linking talcum powder and ovarian cancer to say that "women who used talc-based body powders to powder their genital area have a 33% increased risk of ovarian cancer compared to women who never used the powder," according to the Class Action Complaint, an official court document. Furthermore, the plaintiffs allege that Johnson and Johnson "concealed, suppressed, and/or omitted material facts on the Johnson's Baby Powder product labels and packages ... when they knew, or should have known, that use of Johnson's Baby Powder by

women was not safe and could cause a significant increased risk of ovarian cancer," according to court documents.

Unlike other talcum powder lawsuits** this case did not allege a personal injury resulting from a link between ovarian cancer and talcum powder. Rather, it sought to recover financial losses resulting from the purchase of Johnson's talc-based products. Plaintiffs allege the company was aware of the connection between talcum powder and ovarian cancer, yet failed to warn consumers, resulting in consumers unknowingly purchasing a dangerous product, according to court documents.

In comparison, another case featured on the website was the first successful talcum powder lawsuit, won in South Dakota during 2013.** The plaintiff, Deane Berg, suffered from ovarian cancer and had a multi-decade history of body powder dusting, according to court documents. In that case, a jury determined the plaintiff's diagnosis of ovarian cancer was linked to her use of talcum powder for genital dusting, according to court documents.

For more talcum powder lawsuit news and information, please visit the Talcum Powder Ovarian Cancer Center. The Onder Law Firm is currently accepting inquiries from women and families of women who have suffered from ovarian cancer and have used talcum powder products. Talcum powder lawyers are investigating these inquiries for possible talcum powder cancer claims.

The Onder Law Firm has won major settlements for clients in the areas of drug and medical device recalls, as well as product and family safety. The firm is nationally-renowned for its work on window blind strangulation, and has notable expertise in fighting on behalf of individuals against powerful corporations. Women and family members of women who have been diagnosed with ovarian cancer and have a history of baby powder use are eligible for a free evaluation with a talcum powder attorney, and may contact the firm through its Talcum Powder Ovarian Cancer Center website.

The Onder Law Firm also welcomes talcum powder lawsuit inquiries from other law firms, either to handle these inquiries or work as co-counsel.

About The Onder Law Firm
Onder, Shelton, O'Leary & Peterson, LLC is a St. Louis based personal injury law firm handling serious injury and death claims across the country. Its mission is the pursuit of justice, no matter how complex the case or strenuous the effort. Onder, Shelton, O'Leary & Peterson has represented clients throughout the United States, and other firms throughout the nation often seek its experience and expertise on complex litigation. It is a recognized leader in products liability cases such as window blind cord strangulation and pharmaceutical litigation. The Onder Law Firm's talcum powder lawyers provide information to the public at TalcumPowderOvarianCancerCenter.com.

*Mikhlin and Hoffman et al v. Johnson and Johnson et al, United States District Court in the Eastern District of Missouri, Case No. 4:14-cv-00881-RLW.
**Deane Berg v. Johnson and Johnson Consumer Companies, Inc., U.S. District Court, District of South Dakota, Case No. 09-4179.

EXHIBIT H

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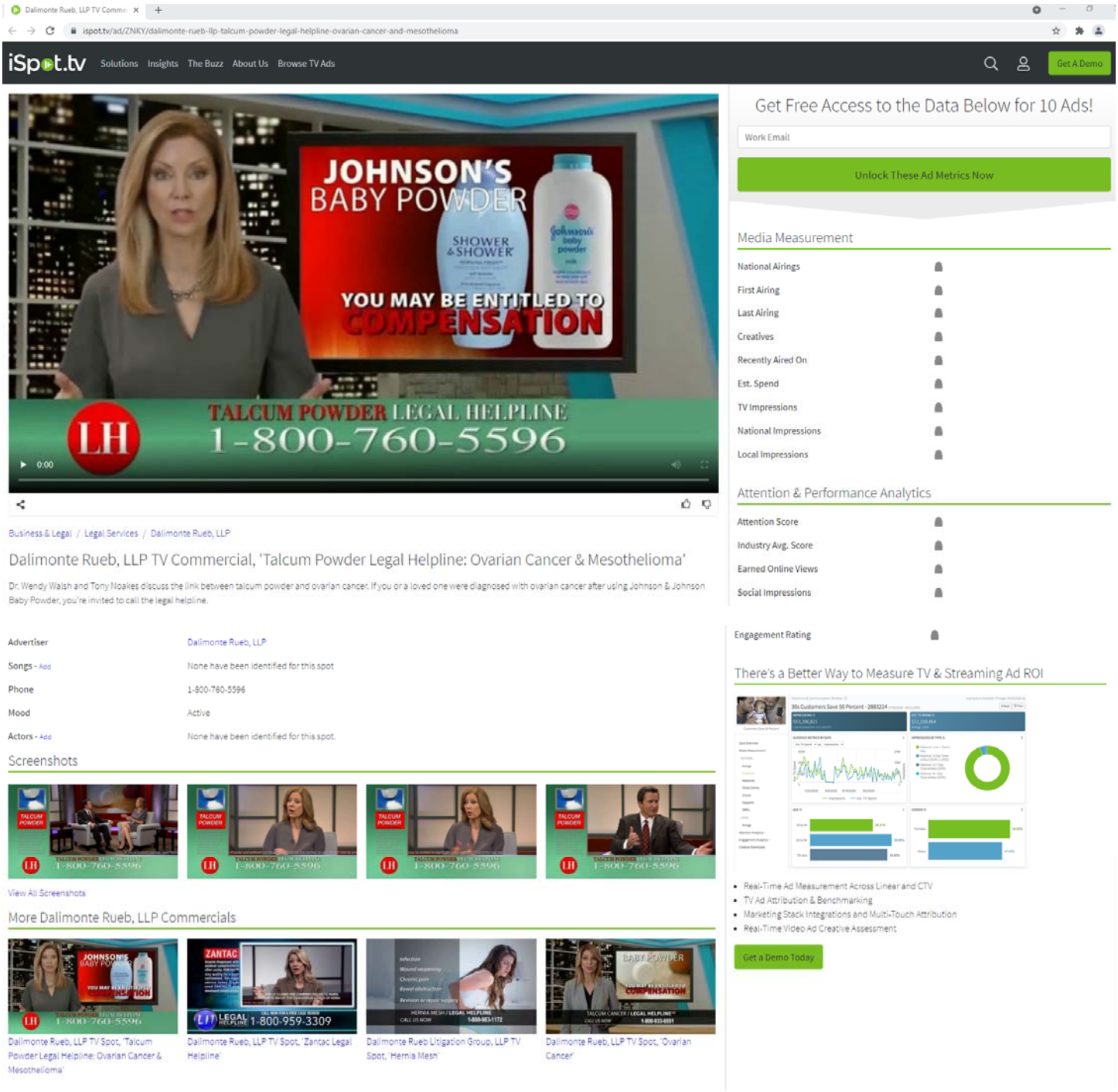
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